Connecticut General Assembly

Public Health Committee Public Hearing

Friday, March 8, 2013

Wesleyan University

Public Testimony Submitted and Support

Proposed Bills:

- **HB – 5140** *AN ACT ESTABLISHING A TASK FORCE TO STUDY LYME DISEASE TESTING*

- **SB – 0368** *AN ACT REQUIRING THE DEPARTMENT OF PUBLIC HEALTH TO REPORT ON LYME DISEASE AND OTHER TICK-BORNE ILLNESSES*

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Connecticut General Assembly
Public Health Committee
Room 3000 – Legislative Office Bldg.
Hartford, CT 06106

March 10, 2013

Distinguished Members of the Public Health Committee;

I would like to thank you for the opportunity to speak before you on March 8, 2013 at Wesleyan University on matters involving **Lyme and Tick-Borne Diseases** in Connecticut. As you heard from many constituents, Lyme and Tick-Borne Diseases is truly a public health threat to the citizens of Connecticut.

As I promised at the public hearing, I have gathered information for you to use when you discern on the **proposed bills HB-5104 and SB-0368** both relating to Lyme and Tick-Borne Diseases. Support for my testimony and as well as for the many questions asked by the Committee can be found in the "Public Testimony Submitted and Support" booklet included herein.

Many testimonies (those you heard on March 8 and those submitted in writing) reveal the true experiences of those who have had the misfortunate to navigate through this complex disease, not only medically, but professionally, politically, psychologically and financially. Due to the complexities, **a well-balanced, scientifically diverse Advisory Committee is truly warranted** to take the time to assess the many challenges that face those who have the disease and those who are at risk (all of our citizens in CT).

Please take the time necessary to read the information and the testimonies of those submitted. I can assure you that these are just the mere few of those currently afflicted with this disease in our state. To help you understand the impact of the citizens around you, I encourage you all to spend a few minutes (where ever you go) asking the question to our citizens, "What do you know about Lyme and Tick-Borne Diseases in Connecticut?" "Have you or anyone you know been effected by this disease?" You will quickly find people all around you who know someone (or many) who have been devastated by this disease. The next time you stop for a cup of coffee, just ask... The next time you are in line at the grocery store, just ask... Please, ask the question to your friends, family, peers, public... understand the need for change in the face of this terrible disease. The health of the Connecticut citizens you represent depend on it.

Respectfully yours,

Marie L. Benedetto

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"Knowing is not enough; we must apply. Willing is not enough; we must do."

Johann Wolfgang von Goethe –

Scientifically and politically minded literary artist (1800s)

"Just because you cannot SEE the pain; Doesn't mean it is not there…."

Mattina Benedetto –

13 year-old Lyme Disease patient for 8 years…

A message to doctors…

On March 8, 2013, my daughter, Mattina Benedetto, spoke before the Public Health Committee articulating her eight-year battle with Lyme and other Tick-Borne Diseases.

Let the **wisdom**, **courage** and **perseverance** she has put forth in facing this Disease and speaking with you, **set the example** you will need to **move forward with** the **change** **so desperately needed** for the citizens of Connecticut in the face of Lyme and Tick-Borne Diseases.

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March 6, 2013 – Senate Bill 0368/HB 5104 – Public Testimony

To Connecticut Public Health Committee:

Summary: My personal experience with Lyme and other Tick-Borne Diseases can be found at the bottom of this testimony. As you will note, my family's experience is not all that different than the many others who have had the unfortunate experience to face this disease and navigate the difficult process of obtaining adequate information and prompt, appropriate diagnosis and care.

Awareness (prevention), Prompt, Appropriate Diagnosis and Care… Sounds like something simple to obtain after a disease well-known to Connecticut for over thirty years.

Ironically that is not the case…

The number of Lyme disease cases in the United States has doubled since 1991. The Centers for Disease Control and Prevention estimate that there are nearly 325,000 new cases each year—**making Lyme disease an epidemic larger than AIDS, West Nile Virus, and Avian Flu combined**. Yet, only a fraction of these cases are being treated, due to inaccurate tests and underreporting. Each year, hundreds of thousands go undiagnosed or misdiagnosed, often told that their symptoms are all in their head.

**Centers for Disease Control (CDC), Infectious Disease Society (IDSA), International Lyme and Associated Disease Society (ILADS), CT Dept. of Public Health, Lyme Organizations (See Agreement Chart)

All Sources Agree (per sourced information**)	**Experience/Challenges (faced by the general public, patient/physician)**
Causes of Lyme and Tick Borne Diseases:	**Causes of Lyme Disease Misunderstood:**
Lyme disease is caused by bacterium – Borrelia burgdoferi	The white-footed mouse lives in all kinds of areas, particularly in people's yards/barns/garages/stonewalls, edges of forest.
90% Reservoir of this bacteria resides in a white-footed mouse - which infects ticks that feed on them	Many people are under the impression that care is only needed if you go for a walk in the woods. Squirrels, foxes and other animals also carry ticks, not just deer.
Transmitted to humans by bite of infected black-legged ticks	Questions arise on how long the tick needs to feed to increase risk of infection
Ticks that transmit Lyme disease also transmit other tick-borne diseases	Co-infections are not commonly known by physicians/public, so symptoms may be missed
Prevalence:	**What really is the prevalence in CT?**
Prevalent across the United States and throughout the World	CT has been the epicenter for Lyme for years… CDC acknowledges 10% underreporting
Most common disease carried by ticks in the United States, and the number of those afflicted is growing steadily—from 10,000** (100,000) reported cases in 1992 to 30,000 in 2009** Underreported 10% - 300,000 cases	CT IS an ENDEMIC area – but how many ticks are infected? With what bacteria or other tick-borne diseases are they infected with that pose a risk to human? Veterinarian reports ¼ dogs are tested positive with Lyme bacteria in Middlesex County
95% of all cases occur in the Northeast/Upper Midwest	Surveillance criteria has changed over time skewing comparison data

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All Sources Agree (per sourced information**)	**Experience/Challenges (faced by the general public, patient/physician)**
CT – 2011 reported 30,380 (based upon underreported 10% and reported 3,380 cases)	Changes in case definition for laboratory and physician reporting has changed over time skewing comparison data
25% of reported cases are children ages 5-19	Local Tick Tests have not been widely performed
Prevention/Awareness:	**How can the Unaware become Aware?**
Most humans are infected through bites of immature ticks called nymphs (size of a poppy seed)	Bites go undetected very often – so the only thing one may be aware of is onset of symptoms
Ticks can attach to any part of the body, but are often attach in hard-to-see areas; groin, armpits, and scalp.	No funding has been made available to do community-based awareness programs
A single tick bite can have debilitating consequences	An infrastructure is in place (local health departments) who are also unaware of this disease and the prevalence of symptoms
Best treatment is prevention/reducing exposure to ticks	Prevention measures (tick checks, showering, covered skin, etc) is fantastic, but not always practical. Young children run in and out all day and will not wear pants/long-sleeve shirts in the summer
Prompt Diagnosis and Treatment	**The average patient sees 5 doctors in 2 years before being diagnosed with Lyme and other Tick-Borne Diseases (lda.org)**
EARLY treatment is KEY to prevent severe illness	If tick bites go undetected, wait until symptoms appear before going to physician
If left untreated, infection can spread to joints, heart and nervous system	Physician doesn't ask about potential exposure to ticks (even though we are in an endemic area) or if the patient remembers a tick attached
Clinical manifestations most often involve; skin, joints, nervous system and heart	General practice, if symptoms are vague – is to wait and see Available information is out-dated – in need of revision
Lyme Disease is diagnosed based on symptoms, physical findings and possibility of exposure to infected ticks	If Practioner suspects Lyme, a test will be ordered Reliability of the tests are in question
Lyme Disease is a CLINICAL diagnosis	Practioner will often use Laboratory tests to DIAGNOSE or RULE OUT the disease
Laboratory testing may be helpful if used and interpreted properly	Laboratory tests are NOT all the same – case definition of positive results are reported based on surveillance guidelines
Healthcare Practitioners in endemic areas should become familiar with the clinical manifestations and recommended practices for diagnosing and treating Lyme and other Tick-Borne Diseases	Many physicians are not aware of any Lyme or other co-infection symptoms other than "achy joints" and "bulls-eye" rash. Neuro symptoms are often missed during this phase. If caught – often standard protocol of antibiotic treatment is not enough (40% often end up with life-time effects of the untreated disease)(lda.org)

"Knowing is not enough; we must apply.
Willing is not enough; we must do."
Johann Wolfgang von Goethe –
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2013 Legislative Proposal: - Senate Bill 0368 and combine House Bill 5104

1. Scientifically Diverse Lyme and Tick-Borne Disease Advisory Committee
   (The language in the bill MUST ensure broad spectrum AND MUST include patient representatives)

2. Review Major Gaps in Understanding the Tick-Borne Diseases

3. Identify Opportunities for:
   a. Coordination of Efforts between agencies/communities and organizations
   b. Additional Funding for Community-Based Programs for Awareness, Physician Awareness, Research and Prevalence testing

4. Report on Findings and Make Recommendations based upon those findings (see VA Lyme Disease Task Force Final Report)

5. Reporting from CT DPH – incorporating two standards of care throughout…
   a. Annual Public Reporting of grants/funding dedicated to Lyme and Tick-Borne Diseases (including community-based awareness programs)
   b. Annual Statistical Reporting
   c. Consistent and updated information on Website regarding disease and associated risks (easily accessible for the unaware)
   d. Coordinated Awareness – State Parks, Schools, Local Communities, etc.

Respectfully Submitted; March 7, 2013
Marie Benedetto, CPA, MST
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Personal Experience – Myself (symptoms started 3/2012 – currently being treated 3/2013)

Infected after playing ball with my children in our front yard in Middlefield. Aching/crackling neck, progressing to shoulders, upper arms, back, hip and right thigh. Muscle twitches/pulses and atrophy, delayed motor skills, slowed speech, slurred speech, muscle weakness, cognitive barriers, double vision (images overlaid), decrease in hearing, ringing in ears, sensitivity to noise, increased irritability, decrease cognitive stamina, not able to spell or speak the right words, unmotivated, migraine headaches, began falling, unable to do anything quickly or concentrate for any extended period of time, right knee/leg felt swollen(big), SPECT scan revealed decrease in blood flow in areas of brain.

Initial visit to general Practioner; tested for Lyme, arthritis and MRI (m.s.)… Per physician, Lyme titer was "negative", recommended a neurologist. In meantime, went to Naturopath, felt symptoms were consistent with Lyme and tested again. The test then came back positive with two I'm (even according to CDC). Called Physician and faxed new results, 4 weeks Doxyclycline ordered. Neurologist confirmed that infection spread through spinal cord based upon symptoms, but was certain that 4 weeks Doxyclycline would be sufficient. I didn't start Doxyclycline until about 8 weeks after initial infection.

By the 4th week, I was symptom free on the Doxyclycline. I knew I couldn't get any more antibiotics from my physician, but also knew-based upon my daughter's experience, that this might not be enough. Sure enough – two weeks after going off the Doxyclycline, all symptoms returned, although not as intense at first, but more severe and systematic overall.

After Lyme Literate Doctor Visit, put on oral antibiotics, but progress slow and worried about decrease blood flow in brain (per SPECT Scan) and consistent cognitive dysfunction. IV therapy ordered – I am nearly symptom free currently (after 10 weeks) while on IV and feel much better. Able to maintain cognitive stamina and seamlessly do the things that became very difficult (e.g. like making a bed, speaking intelligently, spelling).

I KNEW about Lyme disease and KNEW who to go to, and STILL couldn't get treated quickly enough. It is about one year since my symptoms began. I hope that I will be able to recover fully from this ordeal so that I can better take care of my family and balance my work/social life.

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Personal Experience; Marie L. Benedetto – daughter infected

Lyme/co-infected daughter, undiagnosed for 6 years (Age 5 to current age 13)

Symptoms: Chronic fatigue/stamina issues, night sweats, vision, hearing issues, cognitive/fogginess issues, lower body temperature, sleep issues, continued illness, walking/balance issues, food sensitivities, compromised immune system, fevers, neurological dysfunction/weakness on right side of body, excruciating burning shooting pains, paralysis of leg, arm, face, feet, temporary blindness, numbness, memory loss, at times unable to walk or talk, unable to attend her entire fourth-grade year at school, misconception about her academic abilities, etc. etc. A LOT of issues for a young girl that may have been avoided…Reinfection in November 2012, caused tremors, numbness in left hand, feet, legs... in addition, anxiety and social withdrawal from friends.

Treatment from medical community – passive, not knowledgeable, unwilling to link symptoms holistically, general disregard, implied mental illness, even with knowledge of tick bite and risk factors, when diagnosed with Lyme Disease – many medical professionals wouldn't even use the word or acknowledge you. They wouldn't even write it in the medical records even after you told them the history…even after you gave a positive lab report (even according to CDC positive)…

Our actual detailed story of our challenges with the local medical community would send shivers down most parents' spines.. and they would **never** again go to a doctor without using their own sense of self-advocacy armed with knowledge and maintain their own medical history.

Costs Associated: We have spent tens of thousands of dollars (I have actual numbers for submission if you wish) of our own money as insurance companies do not always cover the medical specialty of which is needed to fight this disease. The insurance company has also paid a great portion of various bills adding to the surmounting cost of this disease to our family. If the information was generally accepted and available at the time my daughter became ill, a pediatricians' question "Has she been bit by a tick in the recent past" may have been asked and all of this could have been prevented with a $25.00 bottle of antibiotics. There is no measurable cost to the pain and suffering my daughter (and our family) has endured for the past eight years.

Final Treatment – We needed to go out of state (**New York City**) – it appears if anywhere from New Haven County and North in CT (at the time)– absolutely NO acknowledgement whatsoever that there is even the remote possibility you can contract LYME disease/co-infections.

Received treatment with antibiotics (oral and IV) (3 yrs of treatment) and holistically treated to support immune, endocrine, and nervous system. **Co-infections are significant in her diagnosis and treatment**. She is currently doing well in school, has more stamina, better concentration, stronger immune system. Unfortunately due to the **prolonged disease**, some **permanent damage** may have been done (thyroid and nerve damage) and will continue to have to be monitored for relapses (due to how the bacteria can hide and wait for an opportunity) and then will be treated. She is left with memories of her childhood being ill, in pain/incapacitated at times. Now our fears lie ahead of relapse and will she pass this on in utero should she have a child in her future…it is a possibility that we don't want to face…

Next Steps: Now that my daughter is on a seemingly positive healthy path – I have more time to dedicate my energies to improving the process, awareness and overall good health of the citizens of Connecticut. I want to help the individuals and families avoid the challenges and hurdles we faced in finding the appropriate medical care needed for our daughter. It is devastating to the families and not to mention the victim herself. No child or citizen in the State of Connecticut or anywhere for that matter should have to undergo the scrutiny and general disregard of the medical community that we had to face.

People have sought me out with their own challenges facing them with similar symptoms, stories… I can name over 30 individuals alone who have sought me out in the past year (even perfect strangers) that have the same story…A most powerful realization that came to me in 2009 when my daughter was first diagnosed when I attended a local symposium in Glastonbury to learn more about Lyme Disease. Over 300 people attended this local event, all strangers in the room, yet linked together with the same story…we all experienced similar symptoms, similar medical community pushback and disregard… How can we all be CRAZY? These were just 300+ local people who happened to hear of the event, and happened to be able to make it to the event…all with similar symptoms and stories… That is statistically significant to me.

My hope is that we can come together and provide the awareness necessary to protect the health of our citizens.

Bill Number: S0368

Lyme and Tick-Borne Diseases testimony

Submitted by: Paul Benedetto, Middlefield, CT paulbenedetto@yahoo.com

March 8, 2013

Lyme Disease is a bacterial infection transmitted to humans by the bite of a tick. According to the CT Dept of Public Health, there are more confirmed cases of Lyme Disease in CT in 2011 than any other reported disease except for Chlamydia and Gonorrhea.

I have been a Lyme Disease patient. At present, my wife and daughter are Lyme patients.

As is common amongst those with Lyme Disease, I had persistent symptoms for a number of years that were always unexplainable by each doctor I had visited. I saw general practitioners and specialists, some offering ideas about the cause of my symptoms, some not. However, the symptoms never quite fit the suspected causes. After many years, one doctor suspected Lyme Disease, I was finally diagnosed and was able to be treated.

The difficulties with Lyme disease are too complex and too voluminous to discuss in the three minutes I am permitted to speak at this hearing, so I will note two of them, related to diagnosis.

First, Symptom Variety and Inconsistency.

There is no definitive symptom or set of symptoms that consistently determines a Lyme infection. There can be a wide range of symptoms, many of which can be inconsistent from patient to patient. The variety and inconsistency make it difficult for doctors to make a clinical diagnosis. Imagine how confusing, time-consuming and expensive it is for the patient. Each doctor may be using a different source of information on symptoms and diagnosis. Some doctors will use CDC surveillance criteria as a diagnosis guideline, despite documentation to the contrary.

Second, Blood Testing.

There is no single, definitive test that can determine whether or not a person has a Lyme infection. The blood testing primarily used today does not enjoy universal agreement on what defines a positive result. Different labs will report different sets of data. There are false positives and false negatives. The test is known to be of low accuracy. Despite these shortcomings, many doctors will not perform a clinical diagnosis, but will rule out Lyme disease if they interpret a blood test as negative.

As long as there are difficulties with diagnosis as I have outlined, patients will continue to suffer without adequate treatment.

PUBLIC TESTIMONY –
Senate Bill S0368 – Lyme Disease
March 6, 2013

My name is Mattina Benedetto. I am thirteen years old and live in the town of Middlefield with my parents and brother. I am writing to you about my horrible experience with an awful disease. Lyme Disease. I have been battling Lyme Disease ever since I was the young age of five, but wasn't diagnosed and treated until the age of 10. Since then my life has been drastically changed over long difficult years. My life has not only been changed but dreadfully painful.

Some of my symptoms were (and some still are):
Nerve pain - stabbing shooting pains in arms and legs
Skin pain - like sunburn pain - clothes on my skin would hurt
Aching neck, wrists and knees
Muscle weakness
Intermittent tremors
Soles of my feet would hurt
Always getting sick with fevers/colds/flu's
Intestinal issues
Complete memory loss - didn't even recognize my mother on one severe occasion
Short-Term Memory issues
Fatigue - not able to get out of bed
Paralysis of jaw/tongue, arm, leg
Loss of vision in right eye
Double vision/flashing lights
Feelings of passing out
Numbness in my hands, feet and legs
Chest pains

School
I missed my whole fourth grade year
I felt lonely, helpless and I was annoyed that there was nothing I could do about it.
I missed my friends and wanted to be at school
It was extremely hard to keep up with school work while at home
I would try so hard to do well, but just couldn't do well at school
It is often difficult to find my words - sometimes I just give up speaking

Treatment at Doctors Office
They didn't seem to believe me and it would make me feel horrible. I felt ignored and disrespected.

Treatment:
Finally (after 5 1/2 years) we found a doctor who believed me… and I started the painful process of treatment...
Past three years: pills, supplements and more pills - sometimes up to 7 times a day
IV through port in my chest
Painful weekly shots

Thankfully the treatment has helped me feel much stronger and healthier. My vision issues are gone, the stabbing pains have subsided. I still battle fatigue now and then, but am able to participate in most things with my friends.

Unfortunately, I was bitten again this past November, and have had reoccurrence of many symptoms..... and now I am being treated again... and starting feel better. My left hand is still completely numb; I am starting to get used to it...

I hope my story can help doctors understand better and hopefully believe their patients who have similar symptoms. I hope my story can help others know that they are not alone.

I wish that more people can understand this disease so they don't have to wait six years to get treatment.

The message I want to give to all of the doctors who don't believe their patients...

Just because you cannot ***see*** *the pain - it doesn't mean it is not there...*

Thank you for the opportunity to submit this testimony to the Connecticut Public Health Committee.

Mattina Benedetto

Proposed SB0368/HB5104

Lyme Tick-Borne Diseases
Sources of Information
Agreement Chart

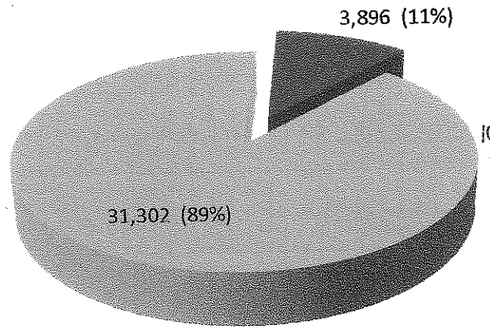
mbenedetto
March 8, 2013
Public Health Committee Hearing

	CDC	IDSA	ILADS	CT DPH	LDA	LD.org	NIH	
Causes of Lyme and Tick-Borne Diseases								
Lyme disease is caused by the bacterium Borrelia burgdorferi and is transmitted to humans through the bite of infected blacklegged ticks.	X	✓	✓	✓	✓	✓		
The ticks that transmit Lyme disease can transmit other tickborne diseases as well.	X	✓	✓	✓	✓	✓		
Prevalance of Lyme and Tick-Borne Diseases								
Prevalant across the United States and throughout the world		✓	X		✓	✓		
Lyme disease is the most common disease carried by ticks in the United States, and the number of those afflicted is growing steadily—from 10,000 reported cases in 1992 to 30,000 in 2009. ***Underreported 10% - 300,000***	X	✓	✓	✓	✓	✓		
Approximately 95 percent of all cases of Lyme disease occur in the Northeast and the Upper Midwest.		X	✓	✓	✓	✓		
Connecticut 2011 - 3038 Lyme Disease (underreported - 10%) ***+30,000***	X	✓	✓	X	✓	✓		
Awareness/Prevention								
Ticks can attach to any part of the human body but are often found in hard-to-see areas such as the groin, armpits, and scalp.	X	✓	✓	✓	✓	✓		
Most humans are infected through the bites of immature ticks called nymphs. Nymphs are tiny (less than 2 mm) and difficult to see;	X	✓	✓	✓	✓	✓		
								Critical Needs Gap
A single tick bite can have debilitating consequences.	X	✓	✓	✓	✓	✓		
The best treatment for Lyme disease is prevention/reducing exposure to ticks	X	X	✓	✓	✓	✓		
Prompt Diagnosis and Treatment								
Early treatment is the key to prevent severe illness		✓	✓	X	✓	✓		
If left untreated, infection can spread to joints, the heart, and the nervous system.	X	✓	✓	✓	✓	✓	X	
Clinical manifestations most often involve the skin, joints, nervous system, and heart		✓	✓	✓	✓	✓		
Lyme disease is diagnosed based on symptoms, physical findings (e.g., rash), and the possibility of exposure to infected ticks; laboratory testing is helpful if used correctly and performed with validated methods.	X	✓	✓	✓	✓	✓		
Lyme and Tick-Borne Diseases is a CLINICAL diagnosis	✓	✓	X	✓	✓	✓		
Health care practitioners, particularly those in areas of endemicity, should become familiar with the clinical manifestations and recommended practices for diagnosing and treating Lyme disease, HGA, and babesiosis (A-III)		X	✓	✓	✓	✓		

X *sourced information*
✓ *agree with sourced information*

Centers for Disease Control (CDC), Infectious Disease Society (IDSA), International Lyme and Associated Diseases Society (ILADS), CT Department of Public Health (DPH), Lyme Disease Association (LDA), Lymedisease.Org (LD.org), National Institute of Health (NIH)

Lyme Disease Association Lyme Disease Analysis
Connecticut / National Reportable Cases [1]



2008 Lyme Disease Reported Cases

10,262

- CT
- US less CT

2009 2010 2011

CT 4156 3,068 3,038 reported

10% 41,560 30,068 30,638

2600-2011 - 35,566 reported + 10% = 355,660

Year	CT Lyme Disease Cases	Adjusted for CDC estimate only 10% cases get reported	US Lyme Disease Cases	Adjusted for CDC estimate only 10% cases get reported
2008 [2]	3,896	38,960	35,198	351,980
2007	3,058	30,580	27,444	274,440
2006	1,788	17,880	19,931	199,310
2005	1,810	18,100	23,305	233,050
2004	1,348	13,480	19,804	198,040
2003	1,403	14,030	21,273	212,730
2002	4,631	46,310	23,763	237,630
2001	3,597	35,970	17,029	170,290
2000	3,773	37,730	17,730	177,300
1999	3,215	32,150	16,273	162,730
1998	3,434	34,340	16,801	168,010
1997	2,297	22,970	12,801	128,010
1996	3,104	31,040	16,455	164,550
1995	1,548	15,480	11,700	117,000
1994	2,030	20,300	13,043	130,430
1993	1,350	13,500	8,257	82,570
1992	1,760	17,600	9,908	99,080
1991	1,192	11,920	9,470	94,700
1990	704	7,040	7,943	79,430
Total 1990 to 2008	45,938	459,380	328,128	3,281,280

25,304

(1) Source data compiled from CDC pub. data (MMWR)

(2) Lyme disease case definition was changed for 2008 and the category of probable was reported for the first time. (US 2008 confirmed = 28,921 / probable = 6,277) (CT 2008 confirmed = 2,738 / probable = 1,158) The numbers used in 2008 include confirmed and probable cases reported by CDC. According to the CDC, only 10% of Lyme disease cases that meet the case definition are reported, meaning if 10,000 cases are reported, 100,000 cases occurred. This data does not include all the cases that fall outside the stringent surveillance case definition.

TABLE B-1 Annual Funding of Tick-Borne Disease Studies by Agency/Organization, 2006–2010

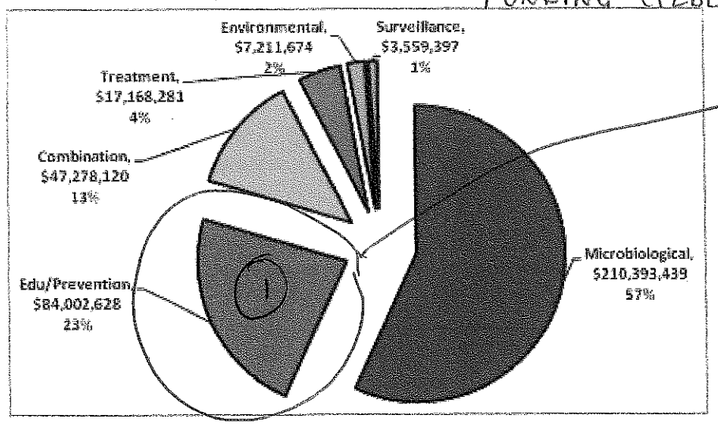
Agency/Org (#)	2006	2007	2008	2009	2010	Average
NIH-NIAID (404)	$91,765,324	$83,686,260	$63,747,787	$73,563,255	—	**$62,552,525**
CDC (19)	$5,706,765	$5,631,765	$5,614,765	$1,226,765	$9,685,126	$5,573,037
NIH-NIAMS (15)	$2,051,376	$2,579,209	$2,758,608	$3,231,214	—	$2,655,102
US-EPA (6)	—	—	—	—	$1,509,759	**$1,509,759**
USDA-ARS (5)	$1,424,000	$1,428,000	$1,447,000	$1,376,000	$1,506,000	$1,436,200
NSF (5)	$390,196	$1,093,733	$1,436,180	$2,990,954	$376,133	$1,256,439
NIH-NINDS (4)	$662,366	$458,834	$654,163	$220,625	$597,877	$518,776
US Army PHC (1)	$237,750	$237,750	$243,500	$232,000	$237,750	$237,750
USDA-NWRC (2)	—	—	—	—	$318,000	$318,000
YEARLY TOTAL	$102,000,027	$94,877,801	$75,902,003	$82,840,813	$12,483,136	**$73,620,756**

From: B, Federal Funding of Tick-Borne Diseases

How much does CT get annually? We don't really know (not easily accessible)

Critical Needs and Gaps in Understanding Prevention, Amelioration, and Resolution of Lyme and Other Tick-Borne Diseases: The Short-Term and Long-Term Outcomes: Workshop Report.
Institute of Medicine (US) Committee on Lyme Disease and Other Tick-Borne Diseases: The State of the Science.
Washington (DC): National Academies Press (US); 2011.

FUNDING (FEDERAL)



* If so many are educated why do we feel uninformed?

FIGURE B-3 Total allocation of funding for tick-borne disease studies by study type, 2006–2010 Cumulative 5 years

From: B, Federal Funding of Tick-Borne Diseases

① Education / Prevention - $84 million —

How much has CT Spent on Education?

"prevention funding" appears to be ONLY research.

Critical Needs and Gaps in Understanding Prevention, Amelioration, and Resolution of Lyme and Other Tick-Borne Diseases: The Short-Term and Long-Term Outcomes: Workshop Report.
Institute of Medicine (US) Committee on Lyme Disease and Other Tick-Borne Diseases: The State of the Science.
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LYME VS. WEST NILE DISPARITY

Table 2: Human Cases of WNV Infection - Connecticut, 2000-2011

2000-2011
LYME
35,566 * 355,660

Total Cases	89
Age range (median)	6-89 (57)
Gender	
Female	42 (47%)
Male	47 (53%)
Syndrome	
Meningitis/Encephalitis	64 (72%)
WNV Fever	24 (27%)
Other Clinical Unspecified	1 (1%)
Fatalities	3 (4%)
Hospitalized	60 (67%)

Same period 2000-2011 WNV = 89
LYME DISEASE = 355,660 — how is this possible?

Table 3: Fatal Human Cases of WNV Infection - Connecticut, 2000-2011

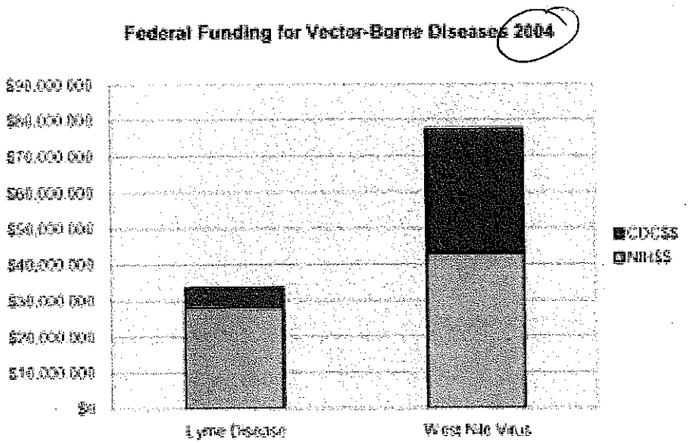
LYME - 40% est: LT Illness
125,000 +

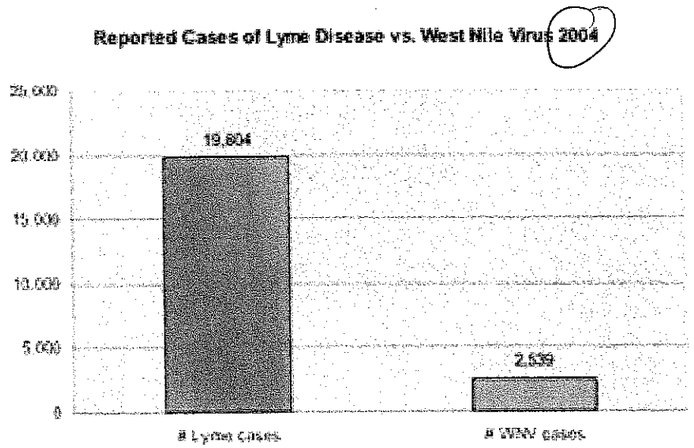
Total Cases	3 deaths
Age range (median)	81-89 (83)
Gender	
Female	2
Male	1
County	
Hartford	1
New Haven	2
Town	
East Haven	1
New Britain	1
New Haven	1
Syndrome	
Meningitis/Encephalitis	3
WNV Fever	0
Other/Clinical Unspecified	0

Table 1: Human Cases of WNV Infection - Connecticut, 2000-2011

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Total
Total Cases	1	6	17	17	1	6	9	4	8	0	11	9	89
Acquired out of CT				2	1	1	1		1				6
Acquired in CT	1	6	17	15		5	8	4	7		11	9	83
Deaths		1				1	1				0	0	3
Age Range (median)	62	37-89 (68)	24-81 (45)	6-85 (55)	78	34-83 (62)	41-81 (63)	48-78 (67)	12-87 (49)		45-81 (54)	45-87 (73)	6-89 (57)
Total by County (Acquired out of CT)													
Fairfield	1	3	8	6	1 (1)	3	3	1	8 (1)		7	6	47 (2)
Hartford		3	6	2		1 (1)	1 (1)	1			2	1	18 (2)
Litchfield				1 (1)									1 (1)
Middlesex				3							1		4
New Haven			3	2		1	5	2			1	2	14
New London				2 (1)									2 (1)
Toliand				1									1
Windham													
Total by Town (Acquired out of CT)													
Ansonia			1										1
Bethlehem				1 (1)									1 (1)
Branford				1									1
Bridgeport		1	2	1			1		3		1	2	9
Bristol					1 (1)		1 (1)						1 (1)
Brookfield											1		1
Colchester				1									1
Coventry				1									1 (1)
Danbury					1 (1)	1		1					2
Darien													1
Durham				1									2
East Haven		1				1			1				5
Fairfield		1		1		1	1		1 (1)		3	1	7 (1)
Greenwich			3				1						1
Hamden								1			1		6
Hartford			3	1									1
Meriden			1										1
Middletown				1									2
New Britain						1						1	2
New Fairfield				1									1
New Haven							3	1			1	2	7
No Haven		1	1										2
No Stonington				1 (1)									1 (1)
Norwalk	1	1		1									3
Plainville			1										1
Sherman									1				1
Simsbury						1(1)							1 (1)
Southington												1	1
Stamford			2	2		1	1		2		1	2	11
Stratford			1										1
Trumbull											1		1
Wallingford				1									1
Westbrook				1									1
West Hartford			2										2
West Haven		1					1						2
Westport											1		1
Wethersfield				1							1		2
Woodbridge								1					1

Disparity in Funding: Lyme vs. West Nile





Lyme disease is almost eight times more commonly reported than West Nile Virus in the U.S., yet the government spends **18 times** more money on each case of WNV.

California Lyme Disease Association 2004

FED FUNDING DISPARITY

CT FUNDING – ?
not available
(or easily accessible)

Connecticut Department of Public Health
Reported Cases of Disease by County - 2011

DISEASE	Fairfield	Hartford	Litchfield	Middlesex	New Haven	New London	Tolland	Windham	Unknown	Total
AIDS see HIV	--	--	--	--	--	--	--	--	--	--
Anaplasmosis (formally known as Ehrlichiosis)	26	0	9	0	1	2	1	2	7	48
Anthrax	0	0	0	0	0	0	0	0	0	0
Babesiosis	13	6	4	6	4	10	2	6	0	51
Botulism (includes infant)	0	0	0	0	0	0	0	0	0	0
Brucellosis	0	0	0	0	0	0	0	0	0	0
California group virus	0	0	0	0	0	0	0	0	0	0
Campylobacter	225	133	23	29	175	40	28	12	0	665
Cat Scratch Disease	NR	NR	NR	NR	NR	NR	NR	NR	NR	--
Cholera	0	0	0	0	0	0	0	0	0	0
Community-associated Clostridium difficile	28	50	3	7	58	2	6	4	0	158
Cryptosporidiosis	7	23	2	1	12	12	8	5	0	70
Cyclospora infection	4	1	2	0	2	0	1	0	0	10
Dengue Fever	0	0	0	0	1	0	0	0	0	1
Diphtheria	0	0	0	0	0	0	0	0	0	0
E.coli O157:H7 gastroenteritis	4	2	2	0	7	1	1	0	0	17
E.coli non-O157, Shiga-toxin producing	8	4	3	0	9	1	2	0	0	27
Eastern Equine Encephalitis (human)	53	44	17	7	36	10	10	2	0	179
Eastern Equine Encephalitis (horses)	NR	NR	NR	NR	NR	NR	NR	NR	NR	--
Giardiasis	53	44	17	7	36	10	10	2	0	179
Group A streptococcal disease, invasive	30	36	6	5	55	9	1	7	0	149
Group B streptococcal disease, invasive	76	114	21	17	113	19	10	8	0	378
H. influenzae type B disease, invasive	0	0	0	0	0	0	0	0	0	0
H. influenzae disease, invasive, other serotypes	14	26	4	0	18	2	2	1	0	67
Hansen's disease (Leprosy)	0	0	0	0	0	0	0	0	0	0
Hemolytic-uremic syndrome	1	1	0	0	0	0	0	0	0	2
Hepatitis A	4	5	0	0	6	2	0	1	0	18
Hepatitis B (acute)	3	2	0	1	11	1	0	1	0	19
Hepatitis B (chronic)	88	88	4	9	109	35	12	1	5	351
Hepatitis C (acute)	3	10	8	5	8	10	2	1	0	47
Hepatitis C (chronic/resolved)	326	508	68	73	505	166	51	83	106	1,886
Hepatitis D	NR	NR	NR	NR	NR	NR	NR	NR	NR	--
HIV	111	120	8	19	125	25	4	11	0	423
Influenza associated deaths, all ages	4	6	1	0	6	0	0	2	0	19
Legionnaires disease	18	28	1	2	24	4	1	3	0	81
Leptospirosis	NR	NR	NR	NR	NR	NR	NR	NR	NR	--
Listeriosis	2	2	1	2	7	2	1	1	0	18
Lyme disease (confirmed)	221	139	86	84	179	216	177	105	796	2,003
Lyme disease (probable)	84	27	32	25	69	98	40	23	637	1,035

NA = Not Available
NR = Not Reportable

* underreported by 10% 30,038 3,038*

Connecticut Department of Public Health
Reported Cases of Disease by County - 2011

DISEASE	Fairfield	Hartford	Litchfield	Middlesex	New Haven	New London	Tolland	Windham	Unknown	Total
Malaria	3	6	0	0	6	4	0	0	0	19
Measles	0	0	0	0	1	0	0	0	0	1
Meningococcal disease	1	0	0	0	2	0	0	0	0	3
Mumps	0	0	0	0	0	0	0	0	0	0
Neonatal sepsis	7	5	0	0	11	0	1	0	0	24
Pertussis	26	10	4	4	13	8	1	2	0	68
Plague	0	0	0	0	0	0	0	0	0	0
Pneumococcal disease, invasive	67	115	17	19	89	22	18	11	0	358
Poliomyelitis	0	0	0	0	0	0	0	0	0	0
Psittacosis	NR	NR	NR	NR	NR	NR	NR	NR	NR	--
Q Fever	0	0	0	0	0	0	0	0	0	0
Rabies (human)	0	0	0	0	0	0	0	0	0	0
Rabies (animal)	43	42	18	12	36	19	19	5	1	195
Reye Syndrome										0
Rheumatic Fever	0	0	0	0	0	0	0	0	0	0
Rocky Mountain Spotted Fever	0	0	0	0	0	0	0	0	0	0
Rotavirus	49	7	5	0	24	9	0	0	0	94
Rubella	0	0	0	0	0	0	0	0	0	0
Salmonellosis	144	98	14	16	106	51	15	26	0	470
Sexually Transmitted Diseases										
Chancroid	NA	NA	NA	NA	NA	NA	NA	NA	NA	0
Chlamydia	2,744	4,223	259	347	4,123	654	267	303	744	13,664
Gonorrhea	436	934	21	71	748	95	31	22	91	2,449
Neonatal Herpes	0	0	0	0	0	0	0	0	0	0
Syphilis (<1 year or early syphilis)	34	26	2	4	43	4	3	6	1	123
Shigellosis	18	11	1	0	8	1	0	2	0	41
Staphylococcus Aureus, Methicillin-resistant, invasive	153	264	54	25	326	51	28	24	0	925
Tetanus	0	0	0	0	0	0	0	0	0	0
Trichinosis	0	0	0	0	0	0	0	0	0	0
Tuberculosis	33	17	2	4	19	7	0	1		83
Typhoid Fever	2	3	0	0	0	0	0	0	0	5
Typhus	NR	NR	NR	NR	NR	NR	NR	NR	NR	--
Varicella (confirmed & probable)	62	71	36	18	59	28	17	13	0	304
Vibrio infections	10	3	0	0	7	4	1	2	0	27
Yellow Fever	0	0	0	0	0	0	0	0	0	0
Yersiniosis	2	1	3	0	1	0	0	0	0	7
West Nile Virus (fever & invasive)	6	1	0	0	2	0	0	0	0	9

NA = Not Available
NR = Not Reportable

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH
Reported Cases of Disease
2000-2005

DISEASE	2000	2001	2002	2003	2004	2005	TOTAL
AIDS	602	587	621	727	672	596	3,805
Anthrax	0	0	1	0	0	0	1
Babesiosis	52	56	106	79	40	136	469
Botulism (includes infant)	0	0	0	1	0	0	1
Brucellosis	0	0	0	0	0	0	0
California group virus	0	1	0	0	0	0	1
Campylobacter	586	495	542	543	585	542	3,293
Cat Scratch Disease	NR	NR	NR	NR	NR	NR	0
Cholera	0	0	0	0	0	0	0
Cryptosporidiosis	29	17	19	20	31	84	200
Cyclospora infection	2	4	7	4	7	35	59
Diphtheria	0	0	0	0	0	0	0
E coli O157:H7 gastroenteritis	84	38	31	37	31	43	264
E coli non-O157, Shiga-toxin producing	13	26	28	30	24	20	141
Eastern Equine Encephalitis (human)	0	0	0	0	0	0	0
Eastern Equine Encephalitis (horses)	0	0	0	2	0	0	2
Ehrlichiosis (Confirmed)	111	46	49	29	34	30	299
Enterococcal disease, vancomycin - resistant	97	150	103	129	NA	NA	479
Giardiasis	462	423	360	368	506	400	2,519
Group A streptococcal disease, invasive	125	129	135	161	93	99	742
Group B streptococcal disease, invasive	286	261	299	273	263	243	1,625
H influenza type B disease, invasive	2	3	2	0	1	2	10
H influenza disease, invasive, other serotypes	48	51	50	44	55	53	301
Hansen's disease (Leprosy)	0	0	2	0	2	1	5
Hemolytic-uremic syndrome	16	2	9	2	5	5	39
Hepatitis A	178	240	96	90	72	51	727
Hepatitis B	49	47	76	98	86	48	404
Hepatitis D	0	0	0	0	1	0	1
Influenza associated deaths, children <18	NR	NR	NR	NR	1	0	1
Legionnaires disease	18	15	19	28	24	35	139
Leptospirosis	0	0	NR	NR	NR	NR	0
Listeriosis	18	15	16	22	18	20	109
Lyme disease	3,773	3,597	4,631	1,403	1,348	1,810	16,562
Malaria	22	28	24	21	23	24	142

Measles	0	1	0	0	0	0	1
Meningococcal disease	19	20	16	15	10	15	95
Mumps	3	0	1	1	0	1	6
Neonatal sepsis	NR	NR	NR	NR	NR	40	40
Pertussis	54	24	30	77	67	86	338
Plague	0	0	0	0	0	0	0
Pneumococcal disease, invasive	665	550	525	451	419	427	3,037
Poliomyelitis	0	0	0	0	0	0	0
Psittacosis	NR	NR	NR	NR	NR	NR	NR
Rabies (human)	0	0	0	0	0	0	0
Rabies (animal)	273	244	331	188	223	210	1,469
Reye Syndrome	0	0	0	0	0	0	0
Rheumatic Fever	0	1	1	0	0	0	2
Rocky Mountain Spotted Fever	0	0	3	0	3	0	6
Rubella	1	0	0	0	0	0	1
Salmonellosis	418	449	456	401	462	468	2,654
Sexually Transmitted Diseases							
Chancroid	0	0	0	0	0	0	0
Chlamydia	7,603	7,718	10,121	9,392	9,557	11,039	55,430
Gonorrhea	2,919	2,546	3,372	3,112	2,861	2,750	17,560
Neonatal Herpes	0	0	0	0	0	0	0
Syphilis	24	32	41	44	169	164	474
Shigellosis	69	60	104	70	68	58	429
Staphylococcus Aureus, Methicillin-resistant, invasive	NR	NR	NR	NR	1,090	1,105	2,195
Tetanus	0	0	0	0	0	1	1
Trichinosis	0	0	0	0	0	0	0
Tuberculosis							
Pulmonary	73	92	76	77	77	64	459
Other	32	28	28	34	24	31	177
Typhoid Fever	8	5	8	8	7	8	44
Typhus	0	0	0	0	0	0	0
Varicella (confirmed & probable)	NR	61	1,816	1,583	1,902	1,709	7,071
Vibrio infections	4	7	6	6	10	12	45
Yellow Fever	0	0	0	0	0	0	0
Yersiniosis	13	9	16	16	19	15	88
West Nile virus (invasive)	0	5	10	12	0	4	31
West Nile virus (fever)	1	1	7	5	1	2	17

NA = Not Available
NR = Not Reportable

Current Legislation in Around the Country
Re: Lyme Tick-Borne Diseases

Website Link	State	Bill No.	Bill Title	Bill Summary	Status 2/26/13	Last Action On Bill
http://www.cga.ct.gov/as	CT	HB05104	An Act Establishing A Task Force To Study Lyme Disease Testing.	To establish a task force to study Lyme disease testing.	Referred to Joint	2/8/2013
http://www.cga.ct.gov/as	CT	HB05297	An Act Establishing A Task Force To Study Lyme Disease Testing.	To establish a task force to study Lyme disease testing.	Referred to Joint	1/15/2013
http://www.cga.ct.gov/as	CT	HB05310	An Act Concerning The Duties Of The Board Of Control For The	To recognize the need to limit certain duties of the Connecticut Agricultural	Public Hearing 01/30	1/25/2013
http://www.cga.ct.gov/as	CT	SB00368	An Act Requiring The Department Of Public Health To Report On	To ensure the state identifies and implements best practices with regard to	Reserved for Subject	2/4/2013
http://www.malegislature.	MA	H989	Relative to Lyme Disease treatment coverage	Relative to Lyme disease treatment coverage. Financial Services.	Senate concurred	1/22/2013
http://legiscan.com/ME/bi	ME	LD597	An Act To Inform Persons of the Options for the Treatment of Lyme	21 This bill directs the Maine Center for Disease Control and Prevention to	On motion by Senator	2/21/2013
http://openstates.org/mt/	MT	SB296	Provide protections for physician treatment of Lyme disease	AN ACT ENTITLED: "AN ACT ESTABLISHING THAT PHYSICIANS MAY NOT	(S) Scheduled for 3rd	2/25/2013
http://legiscan.com/NJ/te	NJ	S1119	Requires health insurers to cover Lyme disease.	This bill requires hospital service corporations, medical service corporations,	Introduced in the Senate,	1/23/2012
http://legiscan.com/NJ/te	NJ	S1638	Codifies Lyme disease reporting requirements.	This bill codifies Lyme disease reporting required by regulation, pursuant to	Received in the	6/21/2012
http://open.nysenate.gov/	NY	A00829	Relates to creating the 21st century workgroup for disease	Relates to creating the 21st century workgroup for disease elimination and	REFERRED TO	1/9/2013
http://open.nysenate.gov/	NY	A03003	Makes appropriations for the support of government - Aid To	Makes appropriations for the support of government - Aid To Localities Budget.	print number 3003b	2/22/2013
part b appropriations	NY	A03004	Makes appropriations for the support of government - Capital	Makes appropriations for the support of government - Capital Projects Budget.	print number 3004b	2/22/2013
http://assembly.state.ny.	NY	A04978	Requires health insurers to provide coverage for long term medical	Requires health insurers to provide coverage for long term medical care for	Referred to INSURANCE	2/13/2013
http://assembly.state.ny.	NY	A05174	Requires health insurers to provide coverage for long term medical	Requires health insurers to provide coverage for long term medical care for	Referred to INSURANCE	2/20/2013
same as A04978	NY	S00541	Requires health insurers to provide coverage for long term medical	Requires health insurers to provide coverage for long term medical care for	Referred to INSURANCE	1/9/2013
same as A00829	NY	S02115	Relates to creating the 21st century workgroup for disease	Relates to creating the 21st century workgroup for disease elimination and	REFERRED TO	1/11/2013
same as A03003	NY	S02603	Makes appropriations for the support of government - Aid To	Makes appropriations for the support of government - Aid To Localities Budget.	PRINT NUMBER 2603B	2/22/2013
same as A03004	NY	S02604	Makes appropriations for the support of government - Capital	Makes appropriations for the support of government - Capital Projects Budget.	PRINT NUMBER 2604B	2/22/2013
same as A05174	NY	S03478	Requires health insurers to provide coverage for long term medical	Requires health insurers to provide coverage for long term medical care for	Referred to INSURANCE	2/4/2013
http://legiscan.com/OR/te	OR	HB2637	Relating to Ixodes pacificus ticks.	Requires Oregon Health Authority to publish and update, at least once every	Public Hearing and	2/8/2013
http://www.legis.state.pa.	PA	SB177	Establishing a task force on Lyme disease and related maladies; and	An Act establishing a task force on Lyme disease and related maladies; and	Referred To Public	1/17/2013
http://legiscan.com/US/bi	US	HB610	To provide for the establishment of the Tick-Borne Diseases	A BILL To provide for the establishment of the Tick-Borne Diseases Advisory	Referred to the House	2/12/2013
http://legiscan.com/US/bi	US	HB611	Lyme and Tick-Borne Diseases Prevention, Education, and Research	A BILL To provide for the expansion of Federal efforts concerning the	Referred to the House	2/12/2013
http://leg1.state.va.us/cgi-	VA	HB1933	Lyme disease; written information to patient when ordering laboratory	Lyme disease; disclosure of information to patients. Requires physicians to	Bill text as passed House	2/22/2013
http://lis.virginia.gov/cgi-	VA	SB683	Tick control; Sunday hunting of deer and permits for application of	Tick control; Sunday hunting of deer and permits for application of acaricides.	Left in Agriculture,	11/30/2012
http://lis.virginia.gov/cgi-	VA	SB971	Lyme disease; physicians to disclose information to patients,	Lyme disease; disclosure of information to patients. Requires physicians to	Failed to pass in Senate	2/23/2013
http://legiscan.com/VT/bil	VT	H0123	An Act Relating To Lyme Disease And Other Tick-borne Illnesses	An Act Relating To Lyme Disease And Other Tick-borne Illnesses	Read First Time and	1/29/2013
http://legiscan.com/VT/bil	VT	S0112	An Act Relating To Lyme Disease And Other Tick-borne Illnesses	An Act Relating To Lyme Disease And Other Tick-borne Illnesses	Read 1st time & referred	2/15/2013

Proposal for CT Bill – Lyme and Tick-Borne Disease Prevention, Education and Research Act

Marie Benedetto – mbenelyme@gmail.com
Caye Helsley - caye@helsley.com
Public Health Committee Public Hearing – March 8, 2013

Purpose: Establish a Tick-Borne Disease Advisory Committee ("**TBDA Committee**") under Proposed Bill: "Lyme and Tick-Borne Disease Prevention Education and Research Act of 2013"

I. Duties of TBDA Committee: Ultimate Goal – *Advise and give recommendations to CT Department of Public Health (and related agencies/organizations) within one year of commencement of TBDA Committee, subsequent year/s ensure recommendations are implemented timely:*

1. **Review Published public/private** treatment guidelines, scientific information, and evaluate such strategies for effective representation of wide diversity of views
2. **Identify Opportunities** to coordinate efforts with Fed/CT/other State agencies and private organizations
3. **Ensure broad spectrum** of scientific viewpoints represented in public health policy decisions and that the information disseminated to public and physicians is balanced
4. **Identify need for funding** for research, physician education, and general public awareness
5. **Make appropriate recommendations** to CT Department of Public Health/Other applicable State Agencies (and/or Governor) on such as **but not limited to**:
   - **Disease Prevention**
   - **Opportunities for cooperative communication** and posting of information between agencies and organizations
   - **Current Testing Methods and Guidelines**
   - **Education (Physician and General Public)**
   - **Research Findings/Funding**
   - **Surveillance**
   - **Other Current Concerns**
     - Animal/Vector Transmission
     - Pregnancy and Sexual Transmission
     - Blood and Organ Donors
     - Children and Effect on Learning in Our Schools (at risk group ages 5-14 *cdc)
     - Other

Proposal for CT Bill – Lyme and Tick-Borne Disease Prevention, Education and Research Act

Marie Benedetto – mbenelyme@gmail.com
Caye Helsley - caye@helsley.com
Public Health Committee Public Hearing – March 8, 2013

II. Make of Up the TBDA Committee (absolutely essential in representing BROAD SPECTRUM of scientific view points)

1. **Appointed Members** as dictated by Public Policy according to General Assembly Guidelines
2. (Additional members as required for subcommittee if TBDA Committee decides prudent)
3. **Not less than 6 members from the scientific community** ***representing broad spectrum of viewpoints held within the scientific community related to Lyme and other Tick-Borne Illnesses***

A. Practicing Physicians Treating Lyme Disease: (not less than 5 years experience in **diagnosing/treating** Lyme Disease and other Tick-Borne illnesses in the latest 7 years) Including but not limited to the following areas:

ILADS members must be included in this process

- Psychology
- Neurology
- Ophthalmology
- Rheumatology
- Pediatrics
- General Practioner
- Infectious Disease
- Other

B. Other Areas of Scientific Expertise:

- Pathology
- International Lyme and Associated Disease Society Experts
- Veterinarian – these drs are aware of the prevelance
- Infectious Disease
- Other as deemed necessary

C. State Agencies:

- Dept. of Agriculture
- Dept. of Public Health
- Dept. of Environment Protection
- Ct. Commission on Children
- Other as deemed necessary

D. Lyme Organizations:

- TBDAlliance
- (1) Lymedisease.org
- (2) Lymediseaseassociation.org
- BLAST – Prevention Program
- Other as deemed necessary

① + ② excellent resources

E. Patient Representatives – experienced in navigating this disease **(Not less than 2 members)**

* must – these are stakeholders and have experienced the challenges that need to be addressed.

Proposal for CT Bill – Lyme and Tick-Borne Disease Prevention, Education and Research Act

Marie Benedetto – mbenelyme@gmail.com
Caye Helsley - caye@helsley.com
Public Health Committee Public Hearing – March 8, 2013

Second Section Proposed:

Proposed Bill Key Points: SB 00368:

Currently Reads: ***AN ACT REQUIRING THE DEPARTMENT OF PUBLIC HEALTH TO REPORT ON LYME DISEASE AND OTHER TICK-BORNE ILLNESSES.*** *(change title name:* **Lyme and Tick-Borne Disease Prevention, Education and Research Act)**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

That chapter 368a of the general statutes be amended to require the Department of Public Health, in consultation with an advisory board established to study Lyme disease, to, not later than September 1, 2013, (1) report to the joint standing committee of the General Assembly having cognizance of matters relating to public health concerning recommendations for best practices to prevent, diagnose and treat Lyme disease and other tick-borne illnesses, and (2) disseminate information to the public and health care providers concerning the prevention and treatment of Lyme disease.

Statement of Purpose:

To ensure the state identifies, reports and implements best practices of incorporating diversified scientific viewpoints with regard to Lyme disease and other tick-borne illnesses.

Reporting from DPH – Statistical/Fiscal and Policy

1) Annual Public Reporting of grants and funding received by DPH designated for Lyme Disease and other tick borne illness (retroactive to 1996 – and continuing annually, designating benefitting communities, and with outcome data/resulting actions)

2) Annual DPH Grants/appropriations for prevention/awareness programs retroactive to 1996 – and continuing annually, designating benefitting communities, and with outcome data/resulting actions)

3) How is DPH utilizing Local Communities and Town/District DPH for public awareness regarding tick-borne diseases?

4) Policy for reviewing website updates/consistencies and diversified scientific viewpoints reported to the public.

Proposal for CT Bill – Lyme and Tick-Borne Disease Prevention, Education and Research Act

Marie Benedetto – mbenelyme@gmail.com
Caye Helsley - caye@helsley.com
Public Health Committee Public Hearing – March 8, 2013

5) Strategies/Policies Short-Term and Long-Term Goals of DPH articulated regarding vector-borne illnesses in the State of CT that:
   a. Ensure that the DPH mission statement is realized
   b. Ensure public/physician awareness programs are effective
   c. Ensure diversified scientific viewpoints
   d. Annual Reporting on effectiveness of these strategies/policies citing challenges and proposed changes to policies/strategies based upon these challenges.
   e. Ensure that information is shared and reported between associated CT Dept. (e.g. Dept. of

6) **Awareness and Education for Public***

Reflecting diversified scientific viewpoints of both:

1) *Infectious Disease Society (IDS – pay for and conduct studies "only science")*
2) *International Lyme and Associated Disease Society – ILADS*
   (Evidence Based Reviews of Studies – not paying for and conduction studies
   Overview of research, meta-analysis)

- Pamphlets at DRs and Summer Camp Programs
- Community health districts – programs and support group information
- Awareness of Prevention – but other things as well – such as symptoms, testing conflicts, differing opinions
- Schools –(see Greenwich District) (Public and Private) – Through school nurse assoc.
- STATS
- Report on Case Definition in CT vs. Case Definition Nationally – How does CT differ? What is most current in CT and what have been the changes to the criteria over the last 20 years?
- Integration with other CT Depts and Local PH Depts

7) **Changes to Website***
   a. Cannot get there from here – "awareness" starts with those who are unaware. Currently, you have to **KNOW** Lyme and vector-borne illness exists in order to find it on current website.
   b. See proposed changes...
   c. Stats on Surveillance Criteria and CT's criteria for dr. reporting
   d. Stats on Number of incidence – not only current new numbers – but cumulative longer term (see chart)

Proposal for CT Bill – Lyme and Tick-Borne Disease Prevention, Education and Research Act

Marie Benedetto – mbenelyme@gmail.com
Caye Helsley - caye@helsley.com
Public Health Committee Public Hearing – March 8, 2013

Some proposed changes to website:

- Flash Dashboard on **front page of website**: 5 most common reportable diseases in CT (ongoing)
- Featured Links: **Lyme and Tick-Borne Diseases (most commonly reported disease in CT/Nation – absolutely should be a featured Link at all times)**
- **Statistics and Research** – (left side of webpage) No mention of Lyme here at all? (lead, westnile, aids, food borne illness) yet compare stats?
- **Defined User/Focus Group to assist in proposed changes to website**
- **Access to website for "awareness purposes" – should include direct access without having to "know" the word Lyme/Tick-Borne Diseases**

Legislative Guidance:

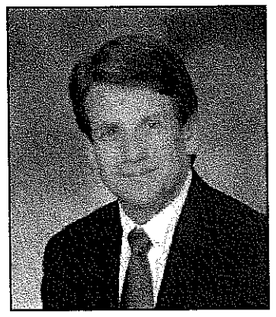
Virginia: Commonwealth of Virginia The Governor's Task Force on Lyme Disease FINAL REPORT Adopted Unanimously on June 30, 2011 (See page 29 of Source Book)

Federal Senate Bill: S1381 (2012) (See page 35 of Source Book)

Other Legislative Proposed/Bills Passed: (see page 24 of Source Book)

VA

The Virginia Governor's Task Force on Lyme Disease Final Report Adopted Unanimously



Michael Farris, Chariman of Governors Task Force

Introduction

In response to reports of the growing number of cases of Lyme disease and other tick-borne illnesses and out of a sense of concern for the significant number of Virginians infected with these diseases, Governor Bob McDonnell and Secretary William Hazel convened this task force to study and make recommendations in the following areas:

Add Surveillance

- ❖ Diagnosis
- ❖ Treatment
- ❖ Prevention
- ❖ Impact on Children
- ❖ Public Education

Add - Physician Education

The Governor and the Secretary appointed the following persons to serve on the Virginia Task Force on Lyme Disease:

Michael Farris, Chairman, The Governor's Task Force on Lyme Disease; Chancellor, Patrick Henry College
Heather Applegate, Ph.D., child psychologist. Supervisor, Diagnostic and Prevention Services, Loudoun County Public Schools and private clinician
Dianne L. Reynolds-Cane, MD, Director, Virginia Department of Health Professions
Douglas W. Domenech, Secretary of Natural Resources, Commonwealth of Virginia
Bob Duncan, Executive Director, Virginia Department of Game and Inland Fisheries, Commonwealth of Virginia
Keri Hall, MD, MS, State Epidemiologist, Virginia Department of Health
William A. Hazel, Jr., MD, Secretary of Health and Human Resources, Commonwealth of Virginia
Kathy Meyer, co-organizer of Parents of Children with Lyme Support Network, Northern Virginia
Samuel Shor, MD, FACP, Associate Clinical Professor George Washington University Health Care Sciences and private practice, Internal Medicine, Reston, VA
Monte Skall, Executive Director, National Capital Lyme and Tick-Borne Disease Association, Mclean, VA
Lisa Strucko, Pharm.D. Clinical Pharmacist, Leesburg Pharmacy, Leesburg, VA
Rand Wachsstock, DVM, veterinarian, Springfield, VA and former instructor in biochemistry at Yale University.

The Task Force held eight separate hearings with two distinct hearing categories.
There were five separate hearings devoted to citizens of Virginia who had been impacted by Lyme and other tick-borne illnesses. These hearings were held in:

- ❖Virginia Beach
- ❖ Richmond
- ❖ Roanoke
- ❖ Springfield
- ❖ Harrisonburg

Over 100 citizens testified at these hearings. We were profoundly impacted by this testimony and thank the citizens for their sacrificial efforts to testify.

A second set of hearings were held devoted to particular topics. At these topical hearings, the bulk of the testimony was from subject matter experts, supplemented by testimonies from citizens that had been asked to focus on the particular issue at hand. The following expert witnesses appeared before our Task Force in these hearings:

Diagnosis & Treatment

Marty Schriefer, MD, Chief of Diagnostic and Reference Laboratory, Centers for Disease Control and Prevention
Daniel Cameron, MD, Past President of International Lyme and Associated Diseases Society, epidemiologist and private practice, Internal Medicine, Mt. Kisco, NY.
Elizabeth L. Maloney, MD, Lyme disease educator and Family Practice physician, Wyoming, MN
Paul G. Auwaerter, MD, representative, Infectious Diseases Society of America Prevention
Charles S. Apperson, Ph.D., Dept. of Entomology, North Carolina State University
Kerry Clark, MPH, Ph.D. Associate Professor, Epidemiology & Environmental Health, Department of Public Health, University of North Florida
David N. Gaines, Ph.D., Public Health Entomologist, VA Department of Health, Office of Epidemiology
J. Mathews (Mat) Pound, Ph.D., Research Entomologist,

USDA-ARS Knipling-Bushland U.S. Livestock Insects Research Service.
Nelson Lafon, Deer Project Leader, VA Department of Game and Inland Fisheries
Impact on Children
Leo J. Shea III, Ph.D., neuropsychologist, Neuropsychological Evaluation & Treatment Services, P.C., New York, NY
Carolyn Walsh, MD, private practice, Internal Medicine, Lansdowne, VA
Daniel E. Keim, MD, private practice, Pediatric Infectious Disease, Fairfax and Leesburg, VA
Jennifer Jones, RN, BSN, NCSN, School Nurse, Trinity Christian School, Fairfax, VA
Public Education
Jorge Arias, Ph.D., entomologist and Supervisor, Disease Carrying Insects Program, Fairfax County Department of Health, Fairfax, VA
Robert Bransfield, MD, President, International Lyme and Associated Diseases Society, Associate Director of Psychiatry and Chairman of Psychiatric Quality Assurance, Riverview Medical Center, and private practice, Psychiatry, Red Bank, NJ
Graham Hickling, Ph.D., Research Associate Professor, University of Tennessee, Director of UT Center for Wildlife Health, Knoxville, TN
Wayne Hynes, Ph.D., Professor and Chair of the Department of Biological Sciences at Old Dominion University, Norfolk, VA
Holly Gaff, Ph.D., Assistant Professor in the Department of Biological Sciences at Old Dominion University, affiliated with the Virginia Modeling, Analysis and Simulation Center, Norfolk, VA.
Peter F. Demitry, MD, MPH, former Assistant Surgeon General, United States Air Force, and current President, 4-D Enterprises, Haymarket, VA

The Task Force made every effort to seek a balanced approach in each of the topical areas where there are recognized divergent views. In general, we were able to find willing witnesses representing a variety of viewpoints on such issues.

We received substantial support from the Virginia Department of Health, Secretary Hazel and the Office of the Secretary of Health and Human Resources for which we offer our deep thanks.

We also received the generous cooperation of a number of public and private organizations, which allowed us to hold our hearings without cost. We thank the following organizations for this valuable contribution:

Patrick Henry College Regent University James Madison

University Roanoke Public Schools (Stonewall Jackson Middle School)

Immanuel Bible Church

Fairfax County Board of Supervisors

Loudoun County Board of Supervisors

Virginia Department of Health Professions

We begin our findings with some general observations that should be considered by all to be non-controversial in character:

General Observations

v Lyme Disease and other tick-borne related illnesses are affecting significant and growing numbers of Virginians
v These diseases are present in every region of Virginia
v Virginia is in a particularly vulnerable geographical location, being at the crossroads of the frontline of expansion of Lyme disease carrying ticks from the North and other tick populations that have entered Virginia from the South, the public health risks of which are uncertain. These diseases can have significant, life-altering impact on patients, especially when the diagnosis is not made shortly after the patient is infected.
v Lyme disease is caused by a spirochete bacterium in the same family as syphilis. It can invade multiple organ systems and has a variable multi-stage progression with a tremendous range of symptoms. It is thought that humans develop no long-term immunity and there is no available vaccine.
v There is much that remains to be understood about Lyme and related diseases in every relevant sector including diagnosis, treatment, and prevention.
v There is an acute need for greater research in all relevant spheres.
v Medical personnel need accurate, fact-based information about prevalence, diagnosis, treatment, and prevention of tick-borne diseases. It is critical to raise awareness in the medical community about Lyme and other tick-borne diseases.
v The mandatory reporting of Lyme disease to the Virginia Department of Health (VDH) can be overlooked or forgotten by some medical providers, leading to an undercount of the number of patients affected.
v The CDC case definition for Lyme disease is for epidemiological purposes only and is not now and never has been the singular valid basis for a diagnosis of Lyme disease.
v Public awareness concerning the prevalence, symptoms and prevention of Lyme disease needs significant expansion.
v Significant improvements that can help to prevent Lyme disease are possible. This will require a concerted, multifaceted effort requiring the cooperation and action of every sector of Virginia-governmental, private, business, community, family, and individual.

General Recommendation:

The task force should recommend that VDH receive funding to enhance its tick-borne diseases program. Key elements of an effective program include the following:

(i) human disease surveillance

(ii) tick surveillance and testing

(iii) general public and healthcare provider outreach and education regarding the prevalence and prevention of Lyme disease.

Any reference to education in these recommendations should emphasize the need to provide an open and balanced review of the full body of literature.

Rationale:

Lyme disease is a significant health issue in Virginia, and VDH has been working to track and prevent spread of this infection over the last decade. As Lyme disease has become increasingly problematic in Virginia during the last five years, surveillance

and prevention activities have become increasingly labor and resource intensive. A strategic public health investment is necessary to enhance VDH's ability to prevent and control the spread of tick-borne diseases.

Specific Findings and Recommendations

In addition to these general observations, we make the following specific findings and recommendations based on the testimony that we received from our hearings:

Diagnosis

1. As acknowledged by the CDC, Lyme disease and many related tick-borne illnesses cannot be adequately diagnosed by serology alone in many cases.

2. There is no serological test that can "rule out" Lyme disease.

3. Clinical diagnosis that may be supported by serology remains the proper method for the diagnosis of Lyme and related illnesses.

4. Clinical diagnosis is not limited to the observation of an EM rash. A significant proportion of patients with Lyme disease may never develop or observe such a rash. Moreover, the EM rash can manifest in non-traditional patterns. The medical community needs a more comprehensive set of visual illustrations so that non-traditional patterns may be properly recognized.

5. Many lay witnesses testified that members of Virginia's medical community inaccurately believed that serology alone can "rule out" Lyme disease.

6. According to lay testimony, there are some members of the Virginia medical community who have refused to consider a diagnosis of Lyme and related illnesses on the ground that "we do not have Lyme in Virginia" or in this "part of Virginia." Lyme disease is present in all parts of Virginia, endemic in most parts of the state, and emerging throughout the Commonwealth.

7. The testimony that came before the Task Force relayed the highly questionable nature of the ELISA test for early localized disease. We encourage the use of clinical judgment at all stages due to the significant limitations of current serology.

8. We recommend that the VDH reporting form include the disclaimer "The CDC case definition is designed for surveillance purposes only. Clinical judgment should be exercised in assessing patients for Lyme disease as meeting the surveillance case definition is not required for the diagnosis of Lyme disease."

9. Since ticks often carry multiple pathogens and we received testimony that many Virginians have multiple tick-borne illnesses that may require comprehensive analysis and treatment, the medical community should be educated on the presence of co-infections.

10. Great caution should be taken whenever a blacklegged tick is attached and especially if it is engorged. Patient reports about the length of time of attachment can be unreliable as some patients may not have observed the exact moment of attachment. Medical providers should be at their liberty to treat Lyme disease prophylactically in such cases because of the high risk of disease. (Note that single-dose prophylaxis may lower the sensitivity of subsequent serology, as stated by the CDC.) Moreover, it is clear that early treatment is very important to prevent many serious complications of Lyme disease.

11. The Task Force encourages increased financial support for Internal Review Board-approved, peer-reviewed clinical studies associated with Lyme disease diagnosis and treatment. The Task Force encourages financial support for Virginia's college and university researchers who undertake research on Lyme or tick-borne disease. This should include all scientific realms. We commend Old Dominion University for undertaking vital research in the Tidewater region. (Rationale: Additional research that investigates the validity and reliability of diagnostic and preventative tools and provides guidance for appropriate treatment will support quality of care and patient outcomes.)

12. The Task Force encourages institutions offering graduate-level medical degrees to offer comprehensive instruction about Lyme and other tick-borne diseases. Due to the rapidly evolving nature of the scientific research and literature on tick-borne disease, medical educators should use due diligence to teach comprehensive and up-to-date information in all aspects of tick-borne disease. (Rationale: Student clinicians (medical, nurse practitioner and physician's assistant students) are the clinicians of the future and should be aware of Lyme and other tick-borne diseases as medical conditions in Virginia.)

13. VDH should continue to provide information to clinicians practicing in the Commonwealth concerning the epidemiology of Lyme disease in Virginia, a physician's responsibility to report Lyme disease, the information VDH requires to classify a case, the purpose of the surveillance case definition, Lyme disease prevention measures and tick identification. VDH should also continue to provide information to clinicians practicing in the Commonwealth about other tick-borne diseases in Virginia. (Rationale: This recommendation articulates VDH's current practice and speaks to its commitment to continue these informational efforts in regard to tick-borne disease, with a particular focus on Lyme disease as it is the most commonly reported tick-borne disease and is present in all parts of Virginia, endemic in most parts of the state and emerging throughout the Commonwealth.)

VDH should emphasize that due to the rapidly evolving nature of the scientific research and literature on Lyme and tick-borne disease, medical professionals should use due diligence to stay abreast of information in all aspects of tick-borne disease to educate their ability to clinically assess patients.

Treatment

1. There is no serological test that can tell a medical provider when a patient has been cured of Lyme disease.

2. A typical criterion that a patient is well is when the symptoms have resolved and the patient feels better.

3. There is no scientific basis for concluding that 30 days or less of antibiotics is sufficient treatment for every case of Lyme disease.

4. We received substantial testimony from lay witnesses that they had been successfully treated with long-term antibiotics.

5. Expert testimony regarding effectiveness of long-term antibiotics conflicted. We encourage additional studies to evaluate the effectiveness of long-term antibiotics as treatment for Lyme disease.

6. The Department of Health Professions should inform its licensees that the department does not target clinicians for disciplinary action by virtue of their antibiotic choice of management of Lyme disease.

7. Lay witnesses expressed displeasure with the propensity of the medical community to treat persons who were ultimately diagnosed as late stage Lyme disease as needing psychological evaluation or treatment. Lay witnesses testified this was often done in a demeaning fashion and appeared as an excuse for the medical community's failure to adequately understand the problem of Lyme disease.

8. Lay witnesses stated that long term treatment of Lyme disease is often not covered by their insurance carriers and that they can spend thousands of dollars per month for their treatment plan. The Committee is unaware of the extent to which this is occurring is unknown to the Task Force and the Task Force recommends that this issue be evaluated by the Bureau of Insurance.

Public Education and Prevention

1. It is a public health goal of a high magnitude to ensure that the general public and medical community become fully aware of the risk of exposure to Lyme and related illnesses and the severe medical consequences that can arise when this disease is not promptly diagnosed and treated. Developing an appropriate sense of public urgency is the greatest single need in the efforts to prevent and treat Lyme disease. The Governor and VDH should expand their current programs of public education to place significant and regular emphasis on Lyme disease so that the public under

"Lyme Task Force"...con't pg 3

standing is proportional to the serious nature of this threat to public health.

2. Since ticks often carry multiple pathogens and we received testimony that many Virginians have multiple tick-borne illnesses that may require comprehensive analysis and treatment, the public should be educated on the presence of co-infections.

3. The VDH and other appropriate state and local agencies should place greater emphasis on public education through modern media. In addition to printed brochures, public interest radio and television ads should be developed. The dramatically amplified. Major internet information organizations-especially those headquartered in Virginia-should be asked to consider donating space for articles and announcements. An increased effort to work with the journalists of Virginia to develop appropriate stories to alert the public should be considered.
For example, Old Dominion University scientists presented their unanticipated discovery of two additional tick species in Tidewater some of which carried an infection that is a cousin of Rocky Mountain Spotted Fever. This example demonstrates the imperative for better communications on all fronts. Budgets appropriate for these purposes should be developed.

4. It is essential that the Virginia approach to Lyme disease prevention and treatment involve collaborative work of all branches of state government and coordination with all facets of local government. The Governor should consider convening a task force of state and local officials to create a best-practices model for government within the Commonwealth. For example, it is imperative that public schools and departments of parks and recreation consult with public health officials to properly manage facilities to prevent unnecessary public exposure to ticks-especially for children-and that warning signs be posted at points of public access in areas that are high-risk.

5. As a part of the efforts to inform the public about safe practices (e.g. how to keep your yard free from ticks), the Commonwealth should clearly communicate the expectation that government agencies actually implement the same methods being recommended to the public. For example, if a public school sends a tick prevention brochure home with a student, but does not actually implement the recommended practices on school property, there are two dangers that arise. First, children are unnecessarily exposed to ticks while at school. Second, the failure of the school to implement the practices signals to the parents that the situation is not truly important. Government must practice what it preaches if the public is going to give Lyme disease prevention the serious attention it deserves.

6. The General Assembly may wish to consider amending the Code of Virginia in order to authorize localities to establish tick surveillance and control districts. (Rationale: Localities are already authorized by the Code to establish mosquito control districts. Providing a mechanism whereby localities could form tick surveillance and control districts could be beneficial to many localities, particularly in Lyme endemic and emerging areas, by allowing the development of practices and policies designed to decrease tick populations on locality property frequented by the general public such as public parks and schools.)

7. The Governor should establish a working group, under the auspices of the Secretary for Natural Resources in collaboration with the Secretary of Health and Human Resources, to develop guidance and potential strategies for localities that wish to

attempt deer and/or tick population control. The Governor should include funding in the 2012 Budget Bill that is sufficient to adequately support this initiative. (Rationale: Developing guidance in this manner will allow for the development of control strategies that are more comprehensive than either Secretariat currently offers in regard to Lyme and other tick-borne diseases.)

8. Public education programs on Lyme prevention should continue to emphasize these (and other) important practices:

Land-use practices for preventing tick exposure:

❖ **Animal exclusion and landscaping**

Homeowners should consider fencing and landscaping choices that tend to exclude deer (the primary adult tick host) and mice (the Lyme bacterium reservoir). Do not plant vegetation that attracts deer, remove food and cover that attracts mice (e.g. wood piles trash), and reduce tick breeding grounds (e.g. clear trees and brush and regularly mow grass). Homeowner associations and other real estate contracts should avoid clauses that restrict the ability of homeowners to effectively exclude deer from their property or control deer populations in their neighborhoods.

❖ **Tick control**

Local, state, and federal agencies should continue to evaluate the utility of host-specific application of acaricides (e.g., USDA 4-poster devices) to combat Lyme disease in this Commonwealth. their use is warranted, the Virginia Department of Game and Inland Fisheries (DGIF) should put in place an orderly and responsible permitting process. DGIF is working with localities to investigate if this tool is a practical solution for managing tick populations. Currently, DGIF is working with Fairfax County on such a study and will develop potential permit conditions that will safeguard wildlife populations and habitats while not inhibiting the use of the 4-poster system. Current regulations and codes exist to allow for the supervised use of these devices. DGIF should work with VDH and local governments to make sure that proper safeguards are put in place and necessary data is collected on the use of these devices. Budget for tick testing should be considered by the General Assembly.

❖ **Deer Control**

DGIF is to be commended for its appropriate expansion of hunting seasons and limits for deer. Further expansions should be considered. Public information campaigns should be conducted to encourage all willing Virginians to participate in an effort to achieve appropriate deer populations for the sake of public health.

❖ **Acaricides**

Public information about the safe and appropriate use of acaricides should be a component of public education efforts.

Human practices to limit exposure to ticks:

❖ **Avoiding tick habitat**

The public needs to be informed about the nature of tick habitat and the danger of entering into such habitat unprepared.

❖ **Appropriate dress and/or repellants** (especially in tick habitats)

When entering such habitat is necessary, the public needs to be informed about best practices to avoid tick exposure (proper dress, repellants, tick checks, etc.)

❖ **Showering after being outdoors**

The public needs to be informed of the value of a thorough shower within a short time after concluding outdoor activities where tick exposure has been possible.

❖ **Evening tick check**

The public should be informed of the necessity of a once-a-day thorough tick check after being outdoors (especially in tick habitat). Children especially should be checked daily.

❖ **Proper pet practices**

Vaccination and repellants for pets should be strongly encouraged. The public should be aware that even though pets have been properly treated, they can still bring ticks into the home that leave the pet and bite a human. Accordingly, indoor pets should be controlled to avoid entry into tick habitat.

Children

1. One expert testified concerning a potential for in utero transmission of Lyme disease. The CDC has proclaimed on its website, "Untreated, Lyme disease can be dangerous to your unborn child."1 VDH should include information for pregnant women in the educational materials that it provides to the general public and to healthcare providers who care for pregnant women.

2. VDH should inform the public of the fact that children are a high-risk group for contracting Lyme disease. Parents need to be alert to the possibility of Lyme-especially when a child presents with symptoms that are not easily categorized as some other illness with an identified etiology.

3. VDH needs to undertake focused campaigns to help educate pediatricians, family practitioners, urgent care clinicians, and other clinicians about the importance of early recognition of Lyme disease.

4. VDH, the Virginia Department of Education, other agencies, and subject matter experts as appropriate should collaborate to create a best practices document focused on children with Lyme and related illnesses. Topics that should be considered include:

❖ Proper construction of school grounds to promote deer exclusion and avoid unnecessary exposure to ticks

❖Before taking students outdoors for instructional field investigations, consideration of the site's likelihood for ticks and then, in cooperation with parents, preparation of the students, parents, and teachers accordingly with the following simple guidelines: wear appropriate clothing, use repellents and perform thorough tick checks. (The benefits of outdoor recreation and education is very important for our children's develop-

ment and complete avoidance of tick habitat would be extremely difficult.)

❖ Proper landscaping and fencing practices to limit the ability of children to enter tick habitat during the school day

❖ Consideration of safe and effective use of acaricides

❖ Education of teachers, school psychologists, school counselors, school nurses, and other professionals in all phases of Lyme disease, but especially in the relationship between Lyme and neurological impairment that may present as learning-related or sudden-onset attention or memory difficulties.

5. VDH should continue to provide information to school nurses in the Commonwealth about Lyme and other tick-borne diseases in Virginia. (Rationale: This recommendation articulates VDH's current practice and speaks to its commitment to continue these critical informational efforts.)

6. Experts testified that students afflicted with this disease often fall significantly behind in school because of the problems that they face, not the least of which are cognitive difficulties. Current educational accommodations are often inadequate.

Consideration should be given to appropriate and sensitive educational modifications for students with late-stage Lyme that help maximize their educational progress and that emphasize the fact that late-stage Lyme disease routinely has waxing and waning symptoms not typical in most chronic medical conditions and that may require novel and timely accommodations and interventions.

7. VDH should continue collaboration with Virginia's Department of Education (DOE), the Virginia Council for Private Education and home schooling associations to explore developing materials that may be incorporated into the science and/or health education curricula of elementary, middle and high school students in the Commonwealth concerning the epidemiology of Lyme and other tick-borne diseases in Virginia, tick-borne disease prevention methods and tick identification. (Rationale: Educating children about Lyme and other tick-borne diseases is best done by presenting this information as part of a school program. A comprehensive approach to educating elementary, middle and high school students about Lyme and other tick-borne diseases can only be achieved through a coordinated effort with the organizations that develop these academic programs for students in Virginia.)

Respectfully submitted,
Michael Farris Chairman

pha

2012 - Bill - (a 2013 bill now exists)

- Balanced/Scientifically Diverse
- Membership Guidelines
- Accountability
- Patient Representative
- Physician Awareness

This bill is special in that it comprehensively + thoughtfully articulates an advisory committee that is balanced.

112TH CONGRESS
1ST SESSION

S. 1381

See "MEMBERSHIP" page 38

To provide for the expansion of Federal efforts concerning the prevention, education, treatment, and research activities related to Lyme and other tick-borne diseases, including the establishment of a Tick-Borne Diseases Advisory Committee.

IN THE SENATE OF THE UNITED STATES

JULY 18, 2011

Mr. BLUMENTHAL (for himself, Mr. REED, Mrs. GILLIBRAND, Mr. WHITEHOUSE, Mr. LIEBERMAN, and Mr. FRANKEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide for the expansion of Federal efforts concerning the prevention, education, treatment, and research activities related to Lyme and other tick-borne diseases, including the establishment of a Tick-Borne Diseases Advisory Committee.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2011".

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Lyme disease is a common but frequently misunderstood illness that, if not caught early and treated properly, can cause serious health problems.

(2) Lyme disease is caused by the bacterium Borrelia burgdorferi, which belongs to the class of spirochetes, and is transmitted to humans by the bite of infected black-legged ticks. Early signs of infection may include a rash and flu-like symptoms such as fever, muscle aches, headaches, and fatigue.

(3) Although Lyme disease can be treated with antibiotics if caught early, the disease often goes undetected because it mimics other illnesses or may be misdiagnosed.

(4) If an individual with Lyme disease does not receive treatment, such individual can develop severe heart, neurological, eye, and joint problems.

(5) Although Lyme disease accounts for 90 percent of all vector-borne infections in the United States, the ticks that spread Lyme disease also spread other diseases, such as anaplasmosis, babesiosis, and tularemia, and carry Bartonella and other strains of Borrelia. Other tick species, such as the aggressive lone star, spread ehrlichiosis, Rocky Mountain spotted fever, and southern tick-associated

rash illness (STARI). Multiple diseases in 1 patient make diagnosis and treatment more difficult.

(6) The Centers for Disease Control and Prevention reported more than 38,000 confirmed and probable Lyme disease cases in 2009. Over the past decade, the incidence of Lyme disease has increased by 84 percent.

(7) According to the Centers for Disease Control and Prevention, from 1992 to 2006, the incidence of Lyme disease was highest among children aged 5 to 14 years of age.

(8) Persistence of symptomatology in many patients without reliable testing makes diagnosis and treatment of patients more difficult.

SEC. 3. ESTABLISHMENT OF A TICK-BORNE DISEASES ADVISORY COMMITTEE.

(a) ESTABLISHMENT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this Act as the "Secretary") shall establish within the Office of the Secretary an advisory committee to be known as the Tick-Borne Diseases Advisory Committee (referred to in this section as the "Committee").

(b) DUTIES.—The Committee shall—

(1) advise the Secretary and the Assistant Secretary for Health regarding the manner in which such officials can—

(A) ensure interagency coordination and communication and minimize overlap regarding efforts to address tick-borne diseases;

(B) identify opportunities to coordinate efforts with other Federal agencies and private organizations addressing such diseases;

(C) ensure interagency coordination and communication with constituency groups;

(D) ensure that a broad spectrum of scientific viewpoints are represented in public health policy decisions and that information disseminated to the public and physicians is balanced; and

(E) advise relevant Federal agencies on priorities related to Lyme and other tick-borne diseases; and

(2) in coordination with relevant agencies within the Department of Health and Human Services, regularly review published public and private treatment guidelines and evaluate such guidelines for effective representation of a wide diversity of views.

(c) MEMBERSHIP.—

(1) APPOINTED MEMBERS.—

(A) IN GENERAL.—From among individuals who are not officers or employees of the Federal Government, the Secretary shall appoint to the Committee, as voting members, the following:

(i) Not less than 4 members from the scientific community representing the broad spectrum of viewpoints held within the scientific community related to Lyme and other tick-borne diseases.

(ii) Not less than 2 representatives of tick-borne disease voluntary organizations.

(iii) Not less than 2 health care providers, including not less than 1 full-time practicing physician, with relevant experience providing care for individuals with a broad range of acute and chronic tick-borne diseases.

(iv) Not less than 2 patient representatives who are individuals who have been diagnosed with a tick-borne disease or who have had an immediate family member diagnosed with such a disease.

(v) At least 2 representatives of State and local health departments and national organizations that represent State and local health professionals.

(B) DIVERSITY.—In appointing members under this paragraph, the Secretary shall ensure that such members, as a group, represent a diversity of scientific perspectives relevant to the duties of the Committee.

(2) EX OFFICIO MEMBERS.—The Secretary shall designate, as nonvoting, ex officio members of the Committee, representatives overseeing tick-borne disease activities from each of the following Federal agencies:

(A) The Centers for Disease Control and Prevention.

(B) The National Institutes of Health.

(C) The Agency for Healthcare Research and Quality.

(D) The Food and Drug Administration.

(E) The Office of the Assistant Secretary for Health.

(F) Such additional Federal agencies as the Secretary determines to be appropriate.

(3) CO-CHAIRPERSONS.—The Secretary shall designate the Assistant Secretary of Health as the co-chairperson of the Committee. The appointed members of the Committee shall also elect a public co-chairperson. The public co-chairperson shall serve a 2-year term.

(4) TERM OF APPOINTMENT.—The term of service for each member of the Committee appointed under paragraph (1) shall be 4 years.

(5) VACANCY.—A vacancy in the membership of the Committee shall be filled in the same manner as the original appointment. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. Members may serve after the expiration of their terms until their successors have taken office.

(d) MEETINGS.—The Committee shall hold public meetings, except as otherwise determined by the Secretary, after providing notice to the public of such meetings, and shall meet at least twice a year with additional meetings subject to the call of the co-chairpersons. Agenda items with respect to such meetings may be added at the request of the members of the Committee, including the co-chairpersons. Meetings shall be conducted, and records

of the proceedings shall be maintained, as required by applicable law and by regulations of the Secretary.

report + recommendation 1 XR

(e) REPORT.—Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Committee, acting through the members representing the Centers for Disease Control and Prevention and the National Institutes of Health, shall submit a report to the Secretary. Each such report shall contain, at a minimum—

(1) a description of the Committee's functions;

(2) a list of the Committee's members and their affiliations; and

(3) a summary of the Committee's activities and recommendations during the previous year, including any significant issues regarding the functioning of the Committee.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated such sums a may be necessary for each of the fiscal years 2012 through 2016. Amounts appropriated under the preceding sentence shall be used for the expenses and per diem costs incurred by the Committee under this section in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), except that no voting

member of the Committee shall be a permanent salaried employee.

SEC. 4. FEDERAL ACTIVITIES RELATED TO THE DIAGNOSIS, SURVEILLANCE, PREVENTION, AND RESEARCH OF LYME AND OTHER TICK-BORNE DISEASES.

(a) IN GENERAL.—The Secretary, acting as appropriate through the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the Director of the Agency for Healthcare Research and Quality, as well as additional Federal agencies as the Secretary determines to be appropriate, and in consultation with the Tick-Borne Diseases Advisory Committee, shall provide for—

(1) the conduct or support of the activities described in subsection (b); and

(2) the coordination of all Federal programs and activities related to Lyme disease and other tick-borne diseases.

(b) ACTIVITIES.—The activities described in this subsection are the following:

(1) DEVELOPMENT OF DIAGNOSTIC TESTS.—Such activities include—

(A) the development of sensitive and more accurate diagnostic tools and tests, including a direct detection test for Lyme disease capable of distinguishing active infection from past infection;

(B) improving the efficient utilization of diagnostic testing currently available to account for the multiple clinical manifestations of both acute and chronic Lyme disease; and

(C) providing for the timely evaluation of promising emerging diagnostic methods.

(2) SURVEILLANCE AND REPORTING.—Such activities include surveillance and reporting of Lyme and other tick-borne diseases—

(A) to accurately determine the prevalence of Lyme and other tick-borne diseases;

(B) to evaluate the feasibility of developing a reporting system for the collection of data on physician-diagnosed cases of Lyme disease that do not meet the surveillance criteria of the Centers for Disease Control and Prevention in order to more accurately gauge disease incidence; and

(C) to evaluate the feasibility of creating a national uniform reporting system including required reporting by laboratories in each State.

(3) PREVENTION.—Such activities include—

(A) the provision and promotion of access to a comprehensive, up-to-date clearinghouse of peer-reviewed information on Lyme and other tick-borne diseases;

(B) increased public education related to Lyme and other tick-borne diseases through the expansion of the Community Based Education Programs of the Centers for Disease Control and Prevention to include expansion of information access points to the public;

(C) the creation of a physician education program that includes the full spectrum of scientific research related to Lyme and other tick-borne diseases, and, in coordination with the Advisory Committee established under section 3, the publication of an annual report that evaluates published guidelines and current research available on Lyme disease, in order to best educate health professionals on the latest research and diversity of treatment options for Lyme disease; and

This is an absolute must— Our CT physicians are so unaware— they need support from CTDPH in expanding their knowledge & Educating them

(D) the sponsoring of scientific conferences on Lyme and other tick-borne diseases, including reporting and consideration of the full spectrum of clinically based knowledge, with the first of such conferences to be held not later than 24 months after the date of enactment of this Act.

(4) CLINICAL OUTCOMES RESEARCH.—Such activities include—

(A) the establishment of epidemiological research objectives to determine the long-term course of illness for Lyme disease; and

(B) determination of the effectiveness of different treatment modalities by establishing treatment outcome objectives.

(c) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purposes of carrying out this section, and for the purposes of providing for additional research, prevention, and educational activities for Lyme and other tick-borne diseases, there is authorized to be appropriated such sums as may be necessary for each of the fiscal years 2012 through 2016.

(2) ADDITIONAL AMOUNTS.—The authorization of appropriations under this subsection is in addition

to any other authorization of appropriations available for the purposes described in paragraph (1).

SEC. 5. REPORTS ON LYME AND OTHER TICK-BORNE DISEASES.

(a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, and annually thereafter, the Secretary shall submit to Congress a report on the activities carried out under this Act.

(b) CONTENT.—Reports under subsection (a) shall contain—

(1) significant activities or developments related to the surveillance, diagnosis, treatment, education, or prevention of Lyme or other tick-borne diseases, including suggestions for further research and education;

(2) a scientifically qualified assessment of Lyme and other tick-borne diseases, including both acute and chronic instances, related to the broad spectrum of empirical evidence of treating physicians, as well as published peer reviewed data, that shall include recommendations for addressing research gaps in diagnosis and treatment of Lyme and other tick-borne diseases and an evaluation of treatment guidelines and their utilization;

(3) progress in the development of accurate diagnostic tools that are more useful in the clinical setting for both acute and chronic disease;

(4) the promotion of public awareness and physician education initiatives to improve the knowledge of health care providers and the public regarding clinical and surveillance practices for Lyme disease and other tick-borne diseases; and

(5) a copy of the most recent annual report issued by the Tick-Borne Diseases Advisory Committee established under section 3 and an assessment of progress in achieving the recommendations included in the Committee's report.

○

General Assembly

Proposed Bill No. 368

January Session, 2013

LCO No. **1904**

The language in this bill must be carefully designed. Please refer to my proposed bill for prior year Federal Senate Bill 51381

Referred to Committee on PUBLIC HEALTH

Introduced by:

SEN. BARTOLOMEO, 13th Dist.

SEN. DOYLE, 9th Dist.

SEN. GERRATANA, 6th Dist.

REP. ABERCROMBIE, 83rd Dist.

REP. FAWCETT, 133rd Dist.

REP. FRITZ, 90th Dist.

REP. LESSER, 100th Dist.

AN ACT REQUIRING THE DEPARTMENT OF PUBLIC HEALTH TO REPORT ON LYME DISEASE AND OTHER TICK-BORNE ILLNESSES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

That chapter 368a of the general statutes be amended to require the Department of

lisease, to, not later than September 1, 2013, (1) report to the joint standing committee of the General Assembly having cognizance of matters relating to publi ıealth concerning recommendations for best practices to prevent, diagnose and reat Lyme disease and other tick-borne illnesses, and (2) disseminate information o the public and health care providers concerning the prevention and treatment o. ,yme disease.

Statement of Purpose:

To ensure the state identifies and implements best practices with regard to Lyme lisease and other tick-borne illnesses.

Lets combine efforts on bills

General Assembly

Committee Bill No. 5104

January Session, 2013

LCO No. **2984**

Referred to Committee on PUBLIC HEALTH

Introduced by:
(PH)

Testing is too narrow of focus – all things are interrelated – This bill will actually hurt patients – I know that is not what is intended – please consider changing the language in this bill.

AN ACT ESTABLISHING A TASK FORCE TO STUDY LYME DISEASE TESTING.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (*Effective from passage*) (a) There is established a task force to study Lyme disease testing. The task force shall review policies for Lyme disease testing in this state and in other states.

This must be a scientifically diverse group (see my proposal)

(b) The task force shall consist of the following members: (See proposal outline)

(1) Two persons experienced in the study of infectious disease, one each appointed by the president pro tempore of the Senate and the speaker of the House of Representatives;

more from varying specialties

(2) Two physicians experienced in treating Lyme disease, one each appointed by the majority leader and the minority leader of the Senate;

last 5 years (not 7 yrs)

Dr. Sin Hang Lee pathologist

Dr. Eva Sapi – University of New Haven

(3) Two persons experienced in the clinical laboratory evaluation of Lyme disease, one each appointed by the majority leader and the minority leader of the House of Representatives;

(4) The Commissioner of Public Health, or the commissioner's

designee; and

(5) A representative of an organization in the state focused on the treatment of Lyme disease, who shall be appointed by the Governor.

(c) All appointments to the task force shall be made not later than thirty days after the effective date of this section. Any vacancy shall be filled by the appointing authority. Members of the task force shall serve without compensation.

(d) The Commissioner of Public Health, or the commissioner's designee, shall serve as chairperson of the task force. The commissioner, or the commissioner's designee, shall schedule the first meeting of the task force, which shall be held not later than sixty days after the effective date of this section. The commissioner, or the commissioner's designee, shall resolve any tie vote of the members.

(e) Not later than January 1, 2014, the task force shall submit a report on its findings and recommendations to the joint standing committee of the General Assembly having cognizance of matters relating to public health, in accordance with the provisions of section 11-4a of the general statutes. Such report shall include, but not be limited to, recommendations for policies concerning Lyme disease testing in the state. The task force shall terminate on the date that it submits its report or January 1, 2014, whichever is later.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*from passage*	New section

Statement of Purpose:
To establish a task force to study Lyme disease testing.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]

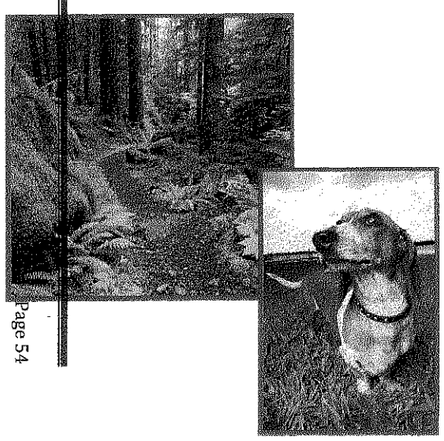
Co-Sponsors: REP. SRINIVASAN, 31st Dist.

H.B. 5104

Prevent Tick Bites

Prevention of Lyme disease and other tick-borne diseases starts with reducing your exposure to tick bites. Tick-borne diseases generally occur during the summer months when ticks are most active. There are no vaccines available for Anaplasmosis, Lyme disease, or Rocky Mountain Spotted fever. To prevent these illnesses you must prevent tick bites. Use the following personal protection measures:

- Avoid tall grass and over-grown areas.
- When hiking stay in the middle of trails.
- Consider using tick repellent.
- Tuck pant leg into socks.
- Wear long-sleeved shirts and closed shoes.
- Wear light-colored clothing to see the ticks easier for removal.
- Examine yourself, your children, and pets for ticks when returning indoors.
- When returning home after an outing, shower using a washcloth or puff to remove unattached ticks .
- Talk to your veterinarian to find out how to protect your pets from tick bites, and the roll of vaccine for dogs.



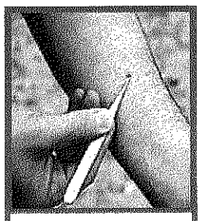
Tick Removal

To remove a tick, use tweezers and grasp the tick's mouthparts as close to the skin as possible. Pull the tick with steady pressure in an upward motion. Don't yank the tick out of your skin. Don't use petroleum jelly, hot matches, nail polish remover, or any other substance to remove a tick. Don't crush the tick's body because it may contain infectious fluids.

When the tick has been removed, wash the area of the bite with soap and water, then apply an antiseptic.

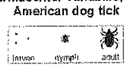
Write on the calendar the date you removed the tick and the part of the body from which it was removed.

Should you experience any symptoms of any diseases mentioned in this brochure within the timeframe indicated, contact your physician to be evaluated.



Ixodes scapularis, black-legged or deer tick.

Dermacentor variabilis, the American dog tick



Actual sizes.

Preventing tick bites is the key to preventing Lyme disease, Anaplasmosis, Babesiosis, and Rocky Mountain Spotted Fever.

Prompt treatment is the key to preventing severe illness.

Connecticut Department of Public Health
Epidemiology and Emerging Infections Program
410 Capitol Avenue, MS# 11EPI
P.O. Box 340308
Hartford, CT 06134-0308
Phone: 860-509-7994
Fax: 860-509-7910
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Connecticut Agricultural Experiment Station
123 Huntington Street
New Haven, CT 06511
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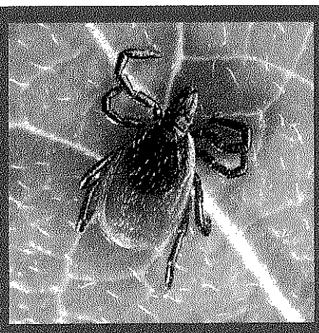
www.ct.gov/caes

Revised 09/24/2012

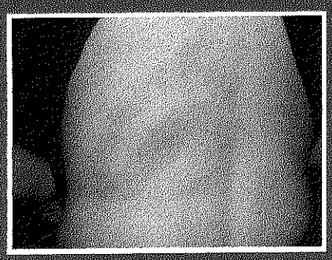
PREVENT TICK-BORNE DISEASES



Lyme Disease & Other Tick-borne Diseases in Connecticut

What You Should Know and What You Should Do

BAN THE BITE



DPH
Connecticut Department of Public Health

Lyme Disease

Lyme disease was first recognized in the United States in the "Lyme", Connecticut area when in 1975 a cluster of children and adults experienced common arthritic symptoms. The disease became physician reportable in Connecticut in 1987. Since then, it has become the most commonly reported tick-borne disease. Although the disease is named after the small town of Lyme, CT, it was recently determined that the disease is thousands of years old. In 2012, researchers announced that the "Iceman" who was found melting out of an Alpine glacier in 1991 had Lyme disease.

Lyme disease is caused by bacteria called *Borrelia burgdorferi*. These bacteria are transmitted through the bite of an infected tick, *Ixodes scapularis*, also known as the black-legged or deer tick. There is a blood test for Lyme disease but it isn't always conclusive.

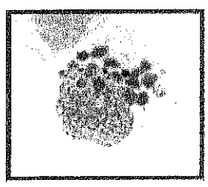
Photo credit: CDC

Symptoms often begin with an expanding red rash around the area of the bite and flu-like symptoms that include muscle aches, fatigue, and fever. These symptoms generally appear 3-32 days after the bite. The early signs of the disease can be overlooked or misdiagnosed. In addition, some people bitten by an infected deer tick do not develop the early symptoms of Lyme disease. If it is not diagnosed and treated promptly, symptoms of Lyme disease may appear weeks to months later causing serious complications of the joints, nervous system, and heart. Lyme disease is treated with antibiotics.

Anaplasmosis

Anaplasmosis (HGA), formerly known as human granulocytic ehrlichiosis (HGE), is caused by bacteria called *Anaplasma phagocytophila*. These bacteria infect white blood cells and are transmitted through the bite of the same tick that causes Lyme disease.

Symptoms of HGA generally include sudden onset of fever, headache, muscle aches, and/or fatigue. Nausea, vomiting, or rash may be present in some patients, although many people infected will not become sick. Illness can range from mild to potentially life threatening. Symptoms occur 7-21 days after the tick bite. Laboratory findings may include thrombocytopenia (decreased number of blood platelets), leukopenia (a decreased number of white blood cells), and/or elevated liver enzymes in the blood. Anaplasmosis may be confused clinically with Rocky Mountain spotted fever (RMSF); however, absence of a prominent rash is a good indicator it is not RMSF. As with Lyme disease, this disease is also treated with antibiotics.



The bacteria that cause human granulocytic anaplasmosis (HGA). CDC

Babesiosis

Babesiosis is caused by a one-cell parasite that infects red blood cells. The parasite, called *Babesia microti*, can be seen within red blood cells when viewed under a microscope. Babesia are most frequently transmitted by the bite of an infected deer tick, and rarely by blood transfusion from an infected donor.

Symptoms of babesiosis may include fever, chills, muscle aches, fatigue and jaundice secondary to hemolytic anemia (destruction of red blood cells). These symptoms may appear 1-4 weeks after the bite. While most people will not become ill, babesiosis can be a potentially severe and sometimes fatal disease. Babesiosis is treated with a combination of medications which usually include quinine and/or clindamycin.

Co-infections

Co-infections are possible through the bite of a single infected deer tick. This means, you can become infected with the microorganisms that cause Lyme disease, anaplasmosis, and babesiosis with a single bite from an infected deer tick. Symptoms from different diseases makes it more difficult for a diagnosis and treatment.

The only way to prevent these diseases is to prevent tick bites.

Rocky Mountain Spotted Fever

Rocky Mountain spotted fever (RMSF) is the most severe and most frequently reported illness caused by rickettsia bacteria, which also cause typhus, in the United States. In Connecticut, RMSF has been reportable since 1980 making it the longest reported tick-borne disease. It is also the least reported tick-borne illness in Connecticut with an average of only 3 cases reported annually.

Rocky Mountain spotted fever is caused by *Rickettsia rickettsii*. Unlike the previously mentioned tick-borne diseases in Connecticut, RMSF is transmitted through the bite of infected *Dermacentor variabilis*, the American dog tick.

Symptoms of RMSF include sudden onset of fever, headache, and muscle pain, followed by a rash. These symptoms may appear 3-14 days after the bite of an infected dog tick. As with other tick-borne diseases, RMSF can be difficult to diagnose in the early stages, and without prompt treatment can cause serious and sometimes fatal illness. This disease is treated with antibiotics.

Treatment

Treatment of tick-borne diseases should begin as soon after infection as possible. Treatment is generally very effective. If you are bitten by a tick, remove the tick as soon as possible. Write on the calendar the date you removed the tick and the part of the body from which it was removed. If you experience any of the symptoms previously mentioned for any of the tick-borne diseases, contact your physician. It will be important for your physician to have a complete history of your exposure to ticks. If you experience an expanding red rash and can not see your physician right away, take a picture of the rash and bring that picture with you at the time of your doctor appointment. Anaplasmosis, Lyme disease, and Rocky Mountain spotted fever are treated with some of the same antibiotics.

Early treatment is the key to prevent severe illness.

Lyme Disease: Two Standards of Care

By Lorraine Johnson, JD, MBA
Executive Director, CALDA

Opinion within the medical community is deeply divided regarding the best approach for treating Lyme disease, particularly persistent Lyme disease that is not cured by short-term protocols. [1-3] This split has resulted in two standards of care. Both viewpoints are reflected in peer-reviewed, evidence-based guidelines. Some physicians treat patients for 30 days only and assume that remaining symptoms reflect a self-perpetuating autoimmune response. [4] Other physicians assume that the persistent symptoms reflect on-going infection and gauge the duration of treatment by the patient's individual clinical response. These physicians believe that there is insufficient evidence at this point to adopt standardized treatment protocols. [5]

While each viewpoint has a strong underlying hypothesis, the scientific evidence supporting either viewpoint is equivocal. Outcomes research is limited and conflicting. The NIAID has only funded three double-blind, placebo-controlled treatment outcome studies for long-term treatment of persistent Lyme disease. The findings of two studies (Klempner and Krupp) are contradictory, with one indicating that continued treatment is beneficial for treating fatigue and the other indicating that it is not.[6-8] The third NIAID-funded study has recently been completed and preliminary results support continued antibiotic treatment for patients with persistent Lyme disease.[9] The findings of five non-controlled studies support continued treatment.[1, 10-13] The existence of limited or conflicting controlled studies is not uncommon in the practice of medicine. When this is the case, of necessity the unique clinical course of the patient bears the laboring oar in treatment decisions.

Insurance companies have placed the full weight of their economic clout behind less expensive short-term treatment protocols. More expensive longer-term treatment options are discredited as "experimental" or "not evidence-based." The point, of course, is that the science underlying both the short-term and the longer-term treatment options is equally uncertain (similar to the situation with treatment of prostate cancer). The appropriate response to equivocal research findings in healthcare outcomes is to fund more research. It is estimated that only 20% of medicine practiced today is rooted in double-blind studies.[14] The bulk of medicine today is practiced in the grey zone. Evidence-based medicine requires only that medicine be practiced in accordance with the evidence that currently exists, not that treatment be withheld pending research.

Insurance companies have adopted guidelines based on short-term treatment approaches. However, the legal standard of care for treating a condition is determined by the consensus of physicians who actually treat patients, not by treatment guidelines.[15] Moreover, more than one standard of care may exist. A number of surveys have found a fairly even split among treating physicians in the case of Lyme disease: One survey found that 57% of responding physicians treat persistent Lyme disease for three months or more.[16] In another survey, "50% of the responders considered using antibiotics for a time greater than one year in a symptomatic seropositive Lyme disease patient. Almost that same number would extend therapy to 18 months if needed."[17] For treating early Lyme disease, there is conflicting evidence. Most physicians responding to one survey specified short-term treatment [18], while 43% of those responding to another survey would treat erythema migrans-positive Lyme disease for three months or more.[16]

When more than one standard of care exists, the critical question becomes *who* decides the appropriate course of treatment for the patient. Under the medical ethical principle of autonomy, the treatment decision belongs to the patient. Hence, the American Medical Association requires that the physician disclose and discuss with the patient not only the risks and benefits of the proposed treatment, but also the risks and benefits of available alternative treatments (regardless of their cost or the extent to which

the treatment options are covered by health insurance).[19] For example, patients with prostate cancer (where significant uncertainty exists regarding long-term treatment outcomes) must elect between watchful waiting, radiation and surgery. The legal doctrine of informed consent also requires that patients be advised of material treatment options. Treatment choices involve trade-offs between the risks and benefits of treatment options that only patients—who know the kinds of risks they are willing to run and the types of quality of life outcomes that matter to them—are uniquely suited to make. [20]

Respect for the basic autonomy of the patient is a fundamental principle of medical ethics. Without adequate information about treatment options, their probable outcomes, and the risks and benefits associated with each, patients cannot act autonomously. Today, however, many patients are either denied treatment by their HMO physicians who follow actuarial treatment protocols generated to keep treatment costs down, or they must find an independent physician to treat them, with the all but foregone conclusion that coverage for this treatment will be denied by their insurer based on cherry-picked (economically favorable) guidelines. Moreover, HMO physicians generally do not advise their patients that treatment alternatives exist.

Scientific uncertainty about Lyme disease has resulted in more than one treatment approach (like prostate cancer). We agree with the AMA, ACP and other professional medical organizations interested in promoting informed patient consent and want to make sure that:

- Physicians, insurers, patients and governmental agencies are educated that two treatment approaches exist;
- Physicians give patients sufficient information about treatment options to enable patients to make a meaningfully informed choice and respect the autonomy of that choice;
- Insurance reimbursement be provided for treatment rendered in accordance with either standard of care; and
- Government agencies provide unbiased information and remain neutral regarding both standards of care and treatment approaches.

References

1. Oksi J, Marjamaki M, Nikoskelainen J Viljanen M, Borrelia burgdorferi detected by culture and PCR in clinical relapse of disseminated Lyme borreliosis. *Ann Med*, 1999; 31(3): 225-32. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=10442678.

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TESTING

Table: Sensitivity/Specificity of Commercial Two-Tier

Testing for Lyme Disease

(ability to detect + test patients who Have the disease) (ability to test to exclude Those who don't)

Study/Year	Sensitivity	Specificity
Schmitz et al, 1993	66%	100%
Engstrom et al, 1995	55%	96%
Ledue et al, 1996	50%	100%
Bakken et al. 1997	75%	81%
Trevejo et al, 1999	29%	100%
Nowakowski et al, 2001	66%	99%
Bacon et al, 2003	68%	99%
Coulter et al, 2005	18%	-
Wormser et al, 2008	14.1%	-
MEAN TOTAL	49.01%	96%

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TWO TIER TESTING - (recommended by CDC)

① ELISA (screening) > "Indirect tests"
② Western Blot Assay

- measure immune system's response to infectious agent rather than confirmation of the infectious agent itself (direct test.) eg. like a strep culture would be "direct"

TESTING

CALDA CDC Survey Results

(182 Respondents)

by Lorraine Johnson, JD, MBA and Theresa Denham

Misuse of the Centers for Disease Control and Prevention (CDC) surveillance criteria for diagnostic purposes is a significant problem for patients with Lyme disease, causing misdiagnosis and treatment delays that may permit the disease to advance from the more easily treated acute infection to a chronic treatment resistant infection. As part of an informal study, a survey questionnaire was distributed to patients with persistent Lyme disease through the Lyme Times publication nationally and through selected doctors' offices throughout the nation during the last quarter of 2003 and throughout 2004. The study was completed in January 2005. Preliminary results suggest widespread misuse of the CDC surveillance criteria for diagnostic purposes resulting in significant diagnostic delays. Respondents were asked to provide a unique patient identifier to ensure that no duplication of results occurred. This article reflects the responses of the 182 respondents that were diagnosed with Lyme disease.

ELISA Misdiagnoses (1)

Seventy-three percent (73%) of respondents were denied a diagnosis for Lyme at least once due to a negative ELISA by CDC criteria. Of these, 31% were denied access to a Western blot (WB) by their physicians due to a negative ELISA.

Western Blot Misdiagnosis (2)

Sixty-one percent (61%) of respondents were denied a diagnosis for Lyme at least once due to a negative WB blot by CDC surveillance band criteria.

ELISA and Western Blot: Misuse of CDC Surveillance Criteria for Diagnostic Purposes

	ELISA	Western blot (CDC surveillance criteria)	Total (non-duplicated)
Misdiagnosis basis	73%	61%	81%
Doctor refused to do Western blot	31%		
Medical Reimbursement Denials	16%	19%	

Method of Diagnosis

Of the diagnostic methods surveyed, only 13% of those responding were diagnosed by ELISA. The WB supported 67% of the Lyme disease cases, with significant bands present and not necessarily falling into the CDC surveillance criteria. Diagnosis by Polymerase Chain Reaction (PCR) and spinal tap were 12 and 3%, respectively. Clinical diagnosis, without supporting lab tests, accounted for 24%.

Diagnosis and Treatment Delays

The misapplication of CDC surveillance criteria (either ELISA or WB) for diagnostic purposes resulted in a delay in diagnosis of one year or more for 49% of responding patients. The average period of delay in diagnosis was almost 4-½ years. A full 81% of patients had physicians fail to diagnose their Lyme disease because of misapplication of the CDC surveillance criteria for diagnosis. Many of these patients incurred treatment delays as well. Delayed diagnoses in Lyme disease can allow the disease to progress from one that is generally treatable to one that is more resistant or unresponsive to treatment, with devastating consequences to the patient.

The table below summarizes the diagnostic delays caused by misuse of the CDC surveillance criteria.

Patients with Lyme disease	**182 (100%)**
Patients with at least one diagnosis failure due to misuse of CDC criteria	**148 (81%)**
Patients with treatment delays of at least one year due to misuse of CDC criteria	**90 (49%)**
Range of delayed treatment duration	**0 to 18 years**
Average delayed treatment duration	**4.4 years**

The take home message of this survey is that 49% of those responding had a delay in diagnosis of one year or greater, with the average delay almost 4-1/2 years. A recent study equated the disability caused by persistent Lyme disease to that of congestive heart failure. Early detection and treatment is key to Lyme disease. The CDC should not tolerate the misuse of surveillance criteria for diagnostic purposes.

CDC Miscommunication will Further Misdiagnosis Problems

In November 2003, doctors, scientists and representatives of several patient education and advocacy groups met with officials from the department of U.S. Human and Health Services (HHS) and the Centers for Disease Prevention and Control (CDC to discuss misuse of the surveillance criteria for diagnosis. As a result of that meeting, the CDC notified physicians that the surveillance case definition was developed for national reporting and is not intended as a surrogate for sound clinical judgment through its Mortality and Morbidity Weekly Report (MMWR).[1, 2]

Surveillance and diagnostic criteria have distinctly different goals,[3] which were explained by Paul Mead in his testimony before the Connecticut Attorney General regarding Lyme disease:

> A clinical diagnosis is made for the purpose of treating an individual patient and should consider the many details associated with that patient's illness. Surveillance case definitions are created for the purpose of standardization, not patient care; they exist so that health officials can reasonably compare the number and distribution of "cases" over space and time. Whereas physicians appropriately err on the side of over-diagnosis, thereby assuring they don't miss a case, surveillance case definitions appropriately err on the side of specificity, thereby assuring that they do not inadvertently capture illnesses due to other conditions....[4]

However, in a recent MMWR, the CDC emphasized its two-tiered testing recommendation and failed to underscore the clinical nature of the diagnosis.[5] Unfortunately, this publication will undoubtedly lead to more misdiagnosis and treatment delays for patients.

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TESTING

Understanding the Western Blot

By Carl Brenner

Revised: September, 1996

Inquiries about various issues relating to Western blot (WB) testing are frequently posted to the Lyme disease discussion groups on the Internet. Among the most commonly asked questions are: What laboratory techniques are used to carry out the assay? What exactly is being measured? What is a "band"? How are the results interpreted? What are the CDC criteria for a "positive" test? Although some of the medical jargon associated with immunology can be a little overwhelming, the scientific principles behind these tests are not difficult to grasp. The following article is offered as a primer in the techniques and interpretation of Western blotting, and should help most patients navigate their way through some of the medical and scientific terminology associated with the assay.

First of all, it should be noted that the Western blot is usually performed as a follow-up to an ELISA test, which is the most commonly employed initial test for Lyme disease. "ELISA" is an acronym for "enzyme-linked immunosorbent assay." There are ELISA tests and Western blots for many infectious agents; for example, the usual testing regime for HIV is also an initial ELISA followed by a confirmatory Western blot.

Both the ELISA and the Western blot are "indirect" tests -- that is, they measure the immune system's response to an infectious agent rather than looking for components of the agent itself. In a Lyme disease ELISA, antigens (proteins that evoke an immune response in humans) from *Borrelia burgdorferi* (Bb) are fixed to a solid-phase medium and incubated with diluted preparations of the patient's serum. If antibodies to the organism are present in the patient's blood, they will bind to the antigen. These bound antibodies can then be detected when a second solution, which contains antibodies to human antibodies, is added to the preparation. Linked to these second antibodies is an enzyme which changes color when a certain chemical is added to the mix. Although the methodology is somewhat complicated, the basic principle is simple: the test looks for antibodies in the patient's serum that react to the antigens present in *Borrelia burgdorferi*. If such antibodies exist in the patient's blood, that is an indication that the patient has been previously exposed to *B. burgdorferi*.

Cross-reacting antibodies

However, many different species of bacteria can share common proteins. Most Lyme disease ELISAs use sonicated whole *Borrelia burgdorferi* -- that is, they take a bunch of *B. burgdorferi* cells and break them down with high frequency sound waves, then use the resulting smear as the antigen in the test. It is possible that a given patient serum can react with the *B. burgdorferi* preparation even if the patient hasn't been exposed to Bb, perhaps because Bb shares proteins with another infectious agent that the patient's immune system *has* encountered. For example, some patients with periodontal disease, which is sometimes associated with an oral spirochete, might test positive on a Lyme ELISA, because their sera will react to components of Bb (like the flagellar protein, which is shared by many spirochetes) even

though they themselves have never been infected with Bb. Therefore, some positive Lyme disease ELISA results can be "false" positives.

To distinguish the false positives from the true positives, a more specific laboratory technique, known as immunoblotting, is used. (The Western blot, which identifies specific antibody proteins, is but one kind of immunoblot; there is also a Northern blot, which separates and identifies RNA fragments, and a Southern blot, which does the same for DNA sequences.) In a Western blot, the testing laboratory looks for antibodies directed against a wide range of Bb proteins. This is done by first disrupting Bb cells with an electrical current and then "blotting" the separated proteins onto a paper or nylon sheet. The current causes the proteins to separate according to their particle weights, measured in kilodaltons (kDa). From here on, the procedure is similar to the ELISA -- the various Bb antigens are exposed to the patient's serum, and reactivity is measured the same way (by linking an enzyme to a second antibody that reacts to the human antibodies). If the patient has antibody to a specific Bb protein, a "band" will form at a specific place on the immunoblot. For example, if a patient has antibody directed against outer surface protein A (OspA) of Bb, there will be a WB band at 31 kDa. By looking at the band pattern of patient's WB results, the lab can determine if the patient's immune response is specific for Bb.

Here's where all the problems come in. Until recently, there has never been an agreed-upon standard for what constitutes a positive WB. Different laboratories have used different antigen preparations (say, different strains of Bb) to run the test and have also interpreted results differently. Some required a certain number of bands to constitute a positive result, others might require more or fewer. Some felt that certain bands should be given more priority than others. In late 1994, the Centers for Disease Control and Prevention (CDC) convened a meeting in Dearborn, Michigan, [1] in an attempt to get everybody on the same page, so that there would be some consistency from lab to lab in the methodology and reporting of Western blot results.

IgG and IgM

Before we get to the recommendations that resulted from this meeting, we need to understand one more facet of the human immune response. Many patients have noticed that their Western blot report is actually comprised of two separate parts, IgM and IgG. These are immunoglobulins (antibody proteins) produced by the immune system to fight infection. IgM is produced fairly early in the course of an infection, while IgG response comes later. Some patients might already have an IgM response at the time of the EM rash; IgG response, according to the traditional model, tends to start several weeks after infection and peak months or even years later. In some patients, the IgM response can remain elevated; in others it might decline, regardless of whether or not treatment is successful. Similarly, IgG response can remain strong or decline with time, again regardless of treatment. Most WB results report separate IgM and IgG band patterns and the criteria for a positive result are different for the two immunoglobulins.

Finally, in setting up a nationwide standard for a positive WB, one makes several assumptions -- that all strains of Bb will provoke similar immune responses in all patients, that all patients will mount a measurable immune response when exposed to Bb, and that the IgG immune response will persist in an infected patient. Unfortunately, none of these is always true. Therefore, a judicious interpretation of Western blot results in a clinical setting

should take into account both the vagaries of the human immune response and the possibility that strain variations in Bb might produce unusual banding patterns.

Official criteria

The CDC criteria for a positive WB are as follows:

* For IgM, 2 of the following three bands: OspC (21-25), 39 and 41. * For IgG, 5 of the following ten bands: 18, OspC (21-25), 28, 30, 39, 41, 45, 58, 66 and 93.

How were these recommendations arrived at? The IgG criteria were taken pretty much unchanged from a 1993 paper by Dressler, Whalen, Reinhardt and Steere [2]. In this study, the authors performed immunoblots on several dozen patients with well characterized Lyme disease and a strong antibody response and looked at the resulting blot patterns. By doing some fairly involved statistical analysis, they could determine which bands showed up most often and which best distinguished LD patients from control subjects who did not have LD. They found that by requiring 5 of the 10 bands listed, they could make the results the most specific, in their view, without sacrificing too much sensitivity. ("Sensitivity" means the ability of the test to detect patients who have the disease, "specificity" means the ability of the test to exclude those who don't. Usually, an increase in one of these measures means a decrease in the other.)

1993 into STILL in place

The IgM criteria were determined in much the same fashion (by different authors in different papers). Fewer bands are required here because the immune response is less mature at this point. Several studies have shown that the first band to show up on a Lyme disease patient's IgM blot is usually the one at 41 kDa, followed by the OspC band and/or the one at 39. The OspC and 39 kDa band are highly specific for Bb, while the 41 kDa band isn't. That's why the 41 by itself isn't considered adequate. Here's the rub, though: the CDC doesn't want the IgM criteria being used for any patient that has been sick for more than a month or two. The thinking here is that by this time an IgG response should have kicked in and the IgM criteria, because they require fewer bands, are not appropriate for patients with later disease.

Criticism of CDC criteria

A number of criticisms have been offered of the CDC criteria since their adoption in 1994. The first is centered on the CDC's failure to make any qualitative distinction among the various bands that can show up on a patient's Western blot. A number of Lyme disease researchers feel that different bands on a WB have different relative importance -- that "all bands are not created equal." For example, many patients with Lyme disease will show reactive bands at, say, 60 and/or 66 kDa. However, these correspond to common proteins in many bacteria, not just Borrelia burgdorferi, and so are of limited diagnostic usefulness, especially in the absence of other, more species-specific bands. The band at 41 kDa corresponds to Bb's flagella (the whip like organelles used for locomotion -- Bb has several) and is one of the earliest to show up on the Western blots of Lyme disease patients. But for some reason it is also the most commonly appearing band in control subjects. This may be due to the fact that many people are exposed to spirochetes at some time in their lives and so their sera might cross react with this protein.

On the other hand, certain other bands are considered highly specific for Bb -- the aforementioned 31 kDa band, for example, or 34 (OspB) or 39 or OspC (anywhere between

21 and 25). The 83 and 94 kDa bands are also thought to be species-specific. Many Lyme disease scientists believe that any patient whose IgG Western blot exhibits bands at, say, any three (or even two) of these locations almost certainly has Lyme disease, regardless of whether or not any other bands are present. They feel that these bands on a Lyme Western blot are simply more meaningful than other, less specific ones and that a rational interpretation of a WB result should take this into account. Unfortunately, this does not often happen, and will happen even less with the new CDC criteria [*Ed. Note: This paper was written in 1996. The criteria have remained the same.*]

1996 – Criteria is STILL The Same.

A second criticism of the CDC Western blot criteria is that they fail to include the 31 and 34 kDa bands. This does indeed seem like an odd decision, since antibodies with these molecular weights correspond to the OspA and OspB proteins of B. burgdorferi, which are considered to be among the most species-specific proteins of the organism. So why didn't Dressler et al. include them? Answer: These bands tend to appear late if at all in Lyme disease patients, and did not show up with great frequency in the patients that the Dressler et al. group studied (though they did show up sometimes). As a result, they weren't deemed to have much diagnostic value and didn't find their way onto the CDC hot list. However, while the absence of either of these bands from a patient's immunoblot result does not rule out Lyme disease, their presence is hardly meaningless. Thus, many Lyme disease experts believe it is a serious mistake to exclude these two antibody proteins from the list of significant bands. The CDC's decision to do so seems particularly strange in light of the fact that it is the OspA component of Bb that is being used as the stimulating antigen in the ongoing experimental Lyme disease vaccine trials. As one immunologist remarked shortly after the 1994 CDC conference, "If OspA is so unimportant, then why the heck are we vaccinating people with it?"

* These bands are specifically EXCLUDED from CDC criteria – even though they are HIGHLY specific to the disease itself. – So much so that these proteins/antibodies were used to vaccinate people w/ LYME Vaccine when it was available on the market.

False negatives

Finally, it is important to keep in mind that no matter how carefully the Western blot test is carried out and interpreted, its usefulness, like that of all tests that measure *B. burgdorferi* antibodies, is ultimately contingent on the reliability of the human immune response as an indicator of exposure to *B. burgdorferi*. There are several scenarios in which the lack of a detectable antibody response may falsely point to a lack of *B. burgdorferi* infection. First, it is well established that early subcurative treatment of Lyme disease can abrogate the human immune response to *B. burgdorferi* [3]. Although this is not thought to be a common phenomenon, a recent comparative trial for the treatment of erythema migrans found that a majority of patients who failed early treatment and suffered clinical relapse were seronegative at the time of relapse [4]. Even treatment for disseminated Lyme disease, in which the patient's IgG immune response was previously well-established, can render a patient seronegative after treatment despite post-treatment culture-positivity for *B. burgdorferi* [5,6].

In addition, patients with Lyme disease may not test positive for exposure to *B. burgdorferi* because their antibodies to the organism are bound up in immune complexes [7]. Once steps are taken to dissociate these immune complexes, free antibody can be detected; however, this is not routinely done when performing serologic tests for Lyme disease. Finally, an indeterminate number of patients with late Lyme disease are simply seronegative for unknown reasons [8]. The actual percentage of such cases as a proportion of all Lyme disease cases is impossible to estimate, since most studies of late Lyme disease enroll only

seropositive patients, which tends to reinforce the circular and erroneous notion that virtually all patients with late Lyme disease are seropositive.

It should also be noted that a positive Western blot is not necessarily an indication of active Lyme disease. A patient's immune response to *B. burgdorferi* can remain intact long after curative treatment for a Lyme infection; therefore, the results of a Western blot assay should always be interpreted in the context of the total clinical picture.

Carl Brenner is a scientist, a member of the Scientific Review Board of the National Research Foundation for Tick Borne Diseases, and former patient representative on the NIH Lyme Disease Advisory Panel.

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* Note - On current lab reports - CDC Surveillance criteria is written on the report as "what is positive for CDC purposes" - The physician often reads that to denote "diagnostic positive/negative" - misleading the physician. Typically further down on the lab report, a note may appear that an "IND" (indeterminent amount) may be clinically significant - but generally physicians do not get that far in reading the report...

Promising Research

"Knowing is not enough; we must apply.
Willing is not enough; we must do."
Johann Wolfgang von Goethe –
Scientifically and politically minded literary artist

Dr. Eva Sapi – University of New Haven – Lyme and Tick-Borne Disease Research Lab

http://www.ctpost.com/local/article/UNH-researcher-may-have-key-to-Lyme-3978859.php
↳ amazing research in our own backyard!

Dr. Sin Hang Lee – Pathologist – Milford (see paper included in this report)

http://www.lyme-disease-research-database.com/lyme_disease_blog_files/category-lyme-disease-tests.html

Dr. Brian Fallon – Columbia University Lyme Research Institute

http://vesta.cumc.columbia.edu/lymedisease/news/user/featNews.php?sel=newsFeat

NIH research – Vaccine of White-footed Mouse to combat Lyme Disease

http://www.ncbi.nlm.nih.gov/pubmed/23428088

(much more evidence exists)

New scientific data is available that speaks to what patients have been experiencing all of these years...

It is time to let science and patients prevail...

Lee et al. BMC Research Notes 2010, 3:273
http://www.biomedcentral.com/1756-0500/3/273

BMC Research Notes

SHORT REPORT Open Access

Early Lyme disease with spirochetemia - diagnosed by DNA sequencing

Sin Hang Lee[1*], Veronica S Vigliotti[1†], Jessica S Vigliotti[1†], William Jones[1†], Jessie Williams[2†], Jay Walshon[2†]

Abstract

Background: A sensitive and analytically specific nucleic acid amplification test (NAAT) is valuable in confirming the diagnosis of early Lyme disease at the stage of spirochetemia.

Findings: Venous blood drawn from patients with clinical presentations of Lyme disease was tested for the standard 2-tier screen and Western Blot serology assay for Lyme disease, and also by a nested polymerase chain reaction (PCR) for *B. burgdorferi* sensu lato 16S ribosomal DNA. The PCR amplicon was sequenced for *B. burgdorferi* genomic DNA validation. A total of 130 patients visiting emergency room (ER) or Walk-in clinic (WALKIN), and 333 patients referred through the private physicians' offices were studied. While 5.4% of the ER/WALKIN patients showed DNA evidence of spirochetemia, none (0%) of the patients referred from private physicians' offices were DNA-positive. In contrast, while 8.4% of the patients referred from private physicians' offices were positive for the 2-tier Lyme serology assay, only 1.5% of the ER/WALKIN patients were positive for this antibody test. The 2-tier serology assay missed 85.7% of the cases of early Lyme disease with spirochetemia. The latter diagnosis was confirmed by DNA sequencing.

Conclusion: Nested PCR followed by automated DNA sequencing is a valuable supplement to the standard 2-tier antibody assay in the diagnosis of early Lyme disease with spirochetemia. The best time to test for Lyme spirochetemia is when the patients living in the Lyme disease endemic areas develop unexplained symptoms or clinical manifestations that are consistent with Lyme disease early in the course of their illness.

Background

Lyme disease is a tick-borne human infection which is an imperative differential diagnosis for internal medicine physicians offering primary care to ambulatory patients in the endemic counties of the United States. Hematogenous dissemination of the *Borrelia burgdorferi* spirochetes from the initial skin site of a tick bite is believed to cause secondary skin lesions and extracutaneous manifestations in Lyme disease [1]. Borrelia spirochetemia, when validated, provides reliable objective evidence for the diagnosis of early Lyme disease, based on which timely appropriate treatment is instituted to avoid tissue damage and to prevent the infection from going into chronic phase. However, *B. burgdorferi* spirochetemia is transient, and the culture techniques which require at least 9 mL of plasma sample and may take several weeks to recover [2] are not practical as a routine diagnostic tool. Pathogenic *Borrelia burgdorferi* cells are known to exist in non-dividing or slowly dividing forms which may not generate a visible positive growth in artificial media at all [3]. The diagnosis of early Lyme disease has been a challenging task for the primary contact physicians practicing in the endemic areas [4].

The polymerase chain reaction (PCR) technologies for the study of the most conserved genospecies-specific *Borrelia burgdorferi* sensu lato16S ribosomal RNA gene, or 16S rDNA, have been used in epidemiology research [5,6]. Using a pair of specific TEC1 and LD2 primers for PCR, the chances of non-specific amplification of 16S rDNA derived from spirochetes unrelated to Lyme disease are minimized [7]. However, little attempt has been made to transfer this procedure into clinical laboratory practice because the method is not robust enough for routine diagnostic applications. We have recently refined this research tool with a nested PCR technology for DNA

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detection, followed by automated direct DNA sequencing for validation of the genospecies-specific *B. burgdorferi* sensu lato 16S rDNA in patient body fluids to further augment the sensitivity and specificity of the procedure as a clinical laboratory test [8]. Since the base sequence of the PCR-amplified spirochete DNA in this procedure is routinely validated by online sequence alignment algorithms with the GenBank database with a 100% identities match with an exclusive unique sequence for the molecular diagnosis to be established, there are no false positive results due to molecular misidentification. The nested PCR technology has increased the sensitivity of the commonly used one-round PCR NAAT for Lyme spirochete DNA by 100-1000 fold [8]. This report summarizes our experience in using this routine clinical laboratory test for molecular diagnosis of *B. burgdorferi* spirochetemia in an endemic suburban town during a summer season.

Methods

From May 1 to November 30, 2009, 463 paired samples of EDTA-anticoagulated venous blood and venous blood without additives from patients suspected of having Lyme disease were received by the Milford Hospital-affiliated Milford Medical Laboratory to be tested for Lyme disease.

Of these 463 pairs of blood samples, 130 were collected on the order of the physicians working in the hospital emergency room (ER) and walk-in clinic (WALKIN) because clinical manifestations of the patients were suggestive of Lyme disease with or without the history of a recent tick bite. Milford is a suburban town in Connecticut in which Lyme disease is endemic.

Milford Hospital is a community hospital. Its ER and WALKIN have about 40,000 patient visits a year. The local residents and practicing physicians are aware that Lyme borreliosis should always be a differential diagnosis during the months from spring to fall when a patient presents with a recent onset of fatigue, skin rash, fever, muscle aches, neck pain, joint pains or lymphadenopathy, without a clear etiology. These symptoms and signs which may vary from patient to patient are recognized as common clinical presentations in early Lyme disease in the United States [9].

The remaining 333 pairs of blood samples were from patients referred by their primary care private physicians in the area for possible Lyme disease.

The 130 ER/WALKIN patients had an age range between 14 and 84 years old with a median age of 42. In comparison, the 333 patients referred from the private physicians' offices had an age range between 11 and 89 with a median age of 51.

For every pair of the blood samples received, the plasma was separated from the EDTA-blood for nested PCR/DNA sequencing for the detection of *B. burgdorferi* 16S rDNA, which was performed at the Milford Medical Laboratory, a clinical laboratory approved by the Department of Public Health, State of Connecticut, under the Clinical Laboratory Improvement Act of 1988 to perform high-complexity laboratory testing, including PCR and DNA sequencing for the molecular identification of *Borrelia burgdorferi*. The latter methodology was published elsewhere [8]. Briefly, a 100 μL aliquot of the patient plasma was mixed with 200 μL 0.7 M ammonium hydroxide in a 1.5 mL Eppendorf tube for DNA extraction. The mixture was heated at 95-98°C for 5 min with closed cap, followed by 10 min with open cap. After the tube was cooled to room temperature, 700 μL of 95% ethanol and 30 μL of 3 M sodium acetate were added to the mixture. The mixture was centrifuged at 13,000 rpm (~16,000 *g*) for 5 min and the supernatant discarded. The precipitate was re-suspended in 1 mL of cold 70% ethanol. Then the suspension was centrifuged at 13,000 rpm for 5 min. After all liquid was discarded, the pellet was air-dried and re-suspended in 100 μL TE buffer with heating at 95-98°C for 5 min. The heated suspension was finally centrifuged at 13,000 rpm for 5 min. One μL of the supernatant was used for primary PCR to be followed by nested PCR amplification without further purification, using a ready-to-use HiFi® DNA polymerase LoTemp® PCR mix (HiFi DNA Tech, LLC, Trumbull, CT) in a total volume of 25 μL. A trace of the primary PCR products without purification was transferred by a micro glass rod to another 25 μL LoTemp® PCR mix containing a pair of heminested (nested) primers for nested PCR amplification.

The primary PCR primers used were nucleotides LD1 (5'-ATGCACACTTGGTGTTAACTA) and LD2 (5'-GAC TTATCACCGGCAGTCTTA) [5]. The nested PCR primers were nucleotides TEC1 (5'-CTGGGGAGTATGC TCGCA AGA) [7] and LD2 [5]. The thermocycling steps were programmed to 30-cycles at 85°C for 30 seconds, 50° C for 30 seconds, and 65°C for 1 minute after an initial heating for 10 minutes at 85°C, with a final extension at 65°C for 10 minutes for both primary and nested PCR in a TC-412 Thermal Cycler (Techne Incorporated, Burlington, NJ). All positive nested PCR products showing a band of expected target size on gel electrophoresis were subjected to direct automated DNA sequencing, using TEC1 nucleotide as the sequencing primer.

The serum sample was submitted for Lyme disease antibody screen by the 2-tier immunoglobulin M (IgM) and immunoglobulin G (IgG) enzyme-linked immunosorbent assay (ELISA) and Western Blot for the detection of antibodies against sonicated whole-cell *B. burgdorferi* by Quest Diagnostics Incorporated, Wallingford, CT, a recognized commercial reference clinical laboratory, according to the CDC guidelines [10].

Publication of general analytical data extracted from hospital records with concealed patient identities was

approved by the Milford Hospital Institutional Review Board.

Results

As previously reported, nested PCR amplification of the conserved segment of *B. burgdorferi* sensu lato 16S rDNA for signature sequence analysis generated a 293 base-pair (bp) amplicon with the TEC1 and LD2 primers. After confirming a 100% identities match with a unique specific DNA sequence for *B. burgdorferi* sensu lato 16S rDNA stored in the GenBank database using the online Basic Local Alignment Search Tool (BLAST), the molecular identification of the nested PCR product as a genomic DNA of *B. burgdorferi* was established beyond a reasonable doubt. BLAST analysis of a 50-60 bp sequence downstream of the LD2 primer-binding site was more than adequate to achieve a very low E-value, which indicates that the chance of molecular misidentification is infinitesimal. A segment of the electropherogram containing the signature nucleotide sequence (Figure 1) was incorporated in the laboratory report for completion of an evidence-based molecular diagnosis of Lyme borrelia spirochetemia.

Our experience confirmed that PCR is not a specific tool for DNA identification, especially for the diagnosis of Lyme disease. From this series of 436 patients, 3 plasma samples were found to contain non-target DNA which led to generation of PCR products of a molecular size similar, but not identical, to that of the *B. burgdorferi* 16S rDNA. These non-Lyme disease DNA molecules were amplified by the PCR primer pair designed for *B. burgdorferi* DNA replication. However, in the absence of a fully matched *B. burgdorferi* target DNA template, these unintended and non-target DNA molecules were amplified by the partially matched primers during the highly sensitive nested PCR process. One of such non-target PCR amplicons was only 6-bp shorter than the expected 293-bp *B. burgdorferi* 16S rDNA fragment, as observed on gel electrophoresis (Figure 2). Only DNA sequencing could confirm that it was really a 287-bp 16S rDNA fragment of an environmental bacterium (Figure 3). As indicated in the GenBank database, the primer binding sites selected for PCR amplification of the most conserved 16S ribosomal RNA gene of the genospecies of *Borrelia burgdorferi* sensu lato also bear great similarities in DNA sequence with the 16S ribosomal RNA genes of other bacterial species (Figure 4).

There was an obvious difference in the test results between the 333 blood sample pairs from the patients referred to the laboratory by the individual private

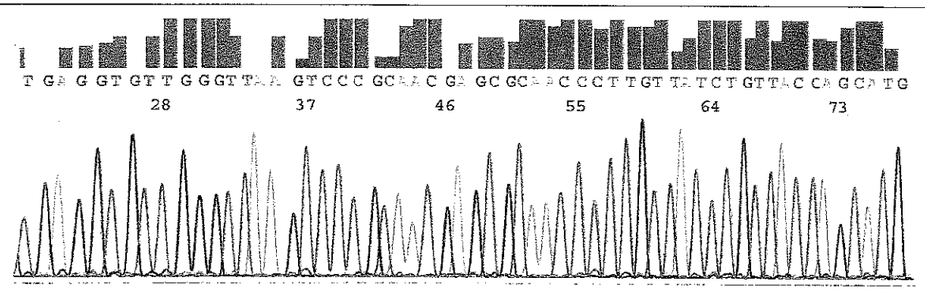

Figure 1 DNA sequencing of *Borrelia burgdorferi* 16S rDNA detected in the plasma of a spirochetemic patient. This 58-base sequence was excised from an electropherogram generated by an ABI 3130 genetic analyzer. The template was the nested PCR amplicon generated by the TEC1 and LD2 primers. The sequencing primer was TEC1. BLAST alignment analysis validates the molecular diagnosis of hematogenous dissemination of Lyme disease in this patient. ABI, Applied Biosystems, Foster City, CA.

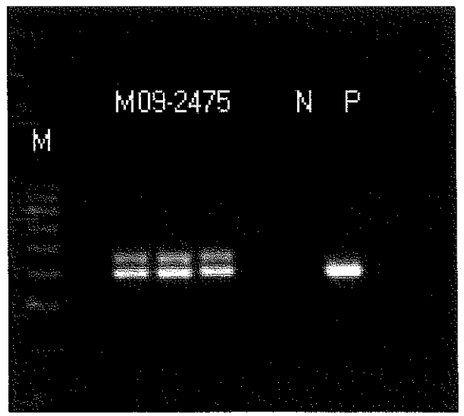

Figure 2 Gel electrophoresis of nested PCR products of DNA from the plasma of a patient suspicious of Lyme disease (M09-2475). The sample was amplified by the TEC1 and LD2 primers and one major band had the molecular weight indistinguishable from the *B. burgdorferi* DNA control. P = *B. burgdorferi* 16S rDNA nested PCR amplicon control; molecular size 293 base pairs. M09-2475 = Nested PCR products of questionable DNA isolated from a patient's plasma. The nested PCR was performed in triplicate to ensure technical accuracy. M = Molecular ruler. N = Negative control to rule out reagent contamination.

practitioners and the 130 blood ample pairs from the patients seen by the physicians at the ER and WALKIN. Of the blood samples from the former group of 333 patients, 28 (28/333), namely 8.4%, were found to be positive for the 2-tier IgM and IgG ELISA screen and further confirmed by Western Blot for the detection of antibodies against sonicated whole-cell *B. burgdorferi*. But all of the 333 companion plasma samples in this group were negative for *B. burgdorferi* nested PCR NAAT, indicating that there was no evidence of spirochetemia in these patients (Table 1).

Of the blood sample pairs collected from the 130 patients visiting the ER and WALKIN, 2 (2/130), namely 1.5%, were found to be positive for the 2-tier Lyme disease serology test, and 7 (7/130), namely 5.4%, were found to contain *B. burgdorferi* 16S rDNA. Of the 2 patients in this group, whose serum was positive for the 2-tier antibody test for Lyme disease, 1 was also found to have circulating *B. burgdorferi* DNA in the companion plasma. The other sero-positive patient did not have evidence of *B. burgdorferi* spirochetemia when the 2-tier Lyme disease antibody test became positive. In other words, among the 7 ER/WALKIN patients presenting with spirochetemia, 6 had *B. burgdorferi* DNA in their blood without the characteristic antibodies while 1 patient had both *B. burgdorferi* DNA and the characteristic Lyme disease antibodies in the blood (Table 2).

At the spirochetemic stage, 3 of the 7 patients had skin rashes. Two of the 3 skin lesions presented with a "bull's eye" appearance, considered typical of Lyme disease, and 1 was described as "hives". Most of the spirochetemic patients (5/7) stated that the duration of their chief complaint symptoms and signs lasted for about 24 hours before they decided to seek immediate medical attention. Two (2/7) of the patients had multiple joint pains or headaches for about 3 weeks before visiting the ER/WALKIN after noticing an additional chest pain or a

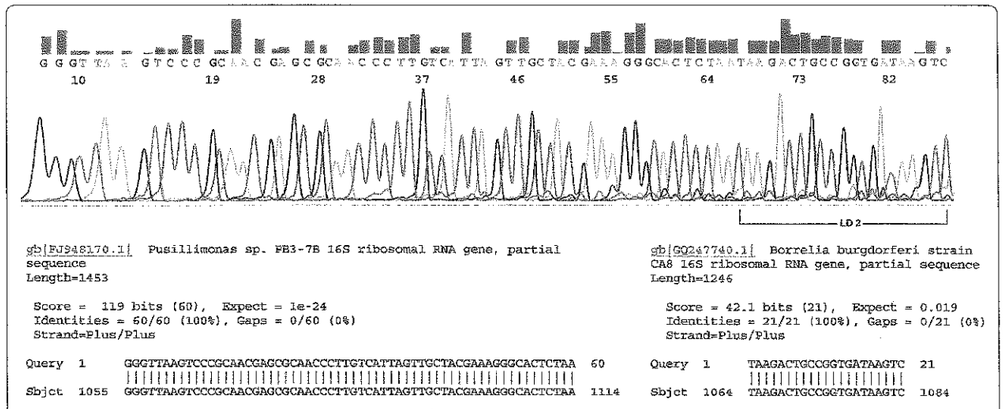

Figure 3 DNA sequencing of the nested PCR products of case M09-2475, as illustrated in Figure 2. The 21-base LD2 PCR primer-binding site for *B. burgdorferi* is marked on the right. A 60-base sequence on the left is validated to be that of a *Pusillimonas* 16S rDNA based on GenBank database. This is a typical example of environmental bacterial 16S rDNA in patient's blood masquerading as *B. burgdorferi* 16S rDNA.

Alignment of the DNA sequences of the two PCR primer binding sites with 10 adjoining bases of *B. burgdorferi* sensu lato 16S rDNA **(a)** against those of an environmental bacterium **(b)** (see Figure 3)

(a) ctggggagtatgctcgcaagagtgaaactcaX-------gggactcagataagactgccggtgataagtc

(b) ctggggagtacggtcgcaagattaaaactcaX000000ggcactctaatgagactgccggtgacaaacc

Figure 4 Two partial DNA sequences retrieved from the National Center for Biotechnology Information database. (a) GenBank Locus GQ247740, a 293-base long signature sequence for *B. burgdorferi* 16S rDNA. TEC1 (left) and LD2 (right) PCR primer sites underlined. **(b)** GenBank Locus FJ948170, a 287-base long sequence of 16S rDNA for numerous environmental bacteria. TEC1 and LD2 primer sites underlined. Note 6 mismatched bases printed in red bold face. X———— = 231 bases in a sequence specific and unique for *B. burgdorferi* 16S rDNA. X = 225 bases in a sequence nonspecific for environmental bacterial 16S rDNA. 000000 = 6 slots with no nucleotide bases. In the absence of a fully matched *B. burgdorferi* DNA, the PCR primers may bind to a partially matched non-target bacterial DNA templates which are not infrequently present in normal human blood. Only DNA sequencing can distinguish the 287 base-pair PCR amplicon of a common environmental bacterial 16S rDNA from a 293-base *B. burgdorferi* 16S rDNA.

skin rash. At the time of the initial visit, none of the spirochetemic patients registered a fever. On 4 patients for whom a CBC was ordered, 3 (3/4) showed slight leukocytosis with an increased percentage of neutrophils. One patient who had a concomitant chronic liver disease showed evidence of leukopenia. None of the 7 spirochetemic patients recalled a history of recent tick bites. As stated above, only one of the 7 spirochetemic patients (1/7) was found to be positive for the 2-tier serology test at the time of the initial visit. Follow-up information obtained from the primary care physicians of the patients confirmed that all presenting clinical symptoms and signs ascribed to Lyme borreliosis resolved completely after treatment with oral doxycycline, without recurrences in the ensuing 6-11 months. Only one of the 6 spirochetemic patients who were serologically negative at the initial visit was re-tested for possible rising antibody titers of Lyme disease, and the serology re-testing result was also negative. The major relevant clinical findings of the 7 spriochetemic patients were summarized in Table 3.

Discussion

Accurate diagnosis of early Lyme disease plays a pivotal role in "curing" the infection with appropriate antibiotic treatment, and in preventing the infection from going into chronic phase which may cause debilitating tissue damage. However, the clinical manifestations of early Lyme disease are highly variable and often not easily distinguished from those caused by other illnesses. The commonly used 2-tier serology laboratory test which usually only turns positive during convalescence of the infection is reported to be negative or non-diagnostic in 75% of the "clinically confirmed" cases of early Lyme disease [4]. Testing for *B. burgdorferi* spirochetemia has been suggested to be the laboratory approach to diagnose early Lyme disease at the stage of hematogenous dissemination of the bacteria, which is believed to

Table 1 Comparison of nested PCR and 2-tier serology in detection of Lyme disease among 333 patients referred by private practitioners from offices

	Two-tier Serology		Total
	+	-	
Nested PCR +	0	0	0
Nested PCR -	28	305	333
Total	28	305	333

+ = positive.

- = negative.

Laboratory detection of Lyme disease among 333 patients referred from private offices:

Confirmed case prevalence = 28/333 = 8.4% (2-tier serology only).

Sensitivity of nested PCR = 0% (0/28).

Sensitivity of 2-tier seropositivity = 100% (28/28).

Table 2 Comparison of nested PCR and 2-tier serology in detection of Lyme disease among 130 patients visiting emergency room and walk-in clinic

	Two-tier Serology		Total
	+	-	
Nested PCR +	1	6	7
Nested PCR -	1	122	123
Total	2	128	130

+ = positive.

- = negative.

Laboratory detection of Lyme disease among 130 ER/walkin patients:

Confirmed case prevalence = (7+1)/130 = 8/130 = 6.2% (DNA sequencing or 2-tier serology).

Sensitivity of nested PCR = 87.5% (7/8).

Sensitivity of 2-tier seropositivity = 25% (2/8).

Table 3 Clinical summary of 7 early Lyme disease patients with spirochetemia

	Age/Sex	Chief Complaint	Duration	Temp °F	CBC Results?	Hx Tick Bite?	Skin Lesion?	Serology	Follow up Serology
1)	43/M	Hives; Thoracic Spine Pain	24 hr	98.0	Not Done	NO	YES	ELISA = +, WB IgM = +	NONE
2)	39/F	Bilateral Leg Pain, Headache	24 hr	98.1	7.2 WBC; Elev Neut%	NO	NO	ELISA = - WB = -	NONE
3)	15/F	Shoulder Pain; Bilateral Leg Pain	24 hr	96.8	4.8 WBC; Elev Neut%	NO	NO	ELISA = -	ELISA = - 2 wks later
4)	43/M	Bull's eye rash	24 hr	98.3	Not Done	NO	YES	ELISA = -, WB = -	NONE
5)	22/M	Painful Inguinal Lymphadenopathy	24 hr	98.6	Not Done	NO	NO	ELISA = -, WB = -	NONE
6)	52/M	Multiple Joint Pain/Chest Pain	3 weeks/72 hr	97.7	10.8 WBC; Elev Neut%	NO	NO	ELISA = -	NONE
7)	55/F	Headache, Bull's eye rash	? 3 weeks	98.5	3.5 WBC; Decreased Neut%	NO	YES	ELISA = -	NONE

precede the appearance of the diagnostic antibodies [1,2,4]. However, the traditional microbiology blood culture techniques are not practical for the diagnosis of Lyme disease because it takes several weeks to recover a positive growth of the Lyme spirochetes in the liquid media. Attempts to culture *B. burgdorferi* spirochetes from patients' blood as a diagnostic tool have largely resulted in disappointments [11]. Non-dividing or slowly dividing *Borrelia burgdorferi* cells which do not generate a discernible positive culture in artificial liquid media are known to cause infections in animals [3]. The other alternative to detect this fastidious infectious agent in a patient's blood is to test for its genetic fingerprint materials, namely by a NAAT.

Several PCR-based nucleic acid amplification tests have been used for the detection of *B. burgdorferi* DNA in the blood samples of patients suffering from Lyme disease. However, their sensitivity is generally too low to be useful for clinical application [12-15] in part due to a lack of consistency of the *Borrelia burgdorferi* genetic materials targeted for PCR amplification by these methods. The lack of rigorous validation of the PCR products has also caused false positive results which can lead to inappropriate treatment with potentially serious complications [16,17]. Adoption of a NAAT procedure for the diagnosis of Lyme disease must proceed with caution.

Since all bacteria contain a 16S ribosomal RNA gene, or 16S rDNA, which differs from one another in their respective unique hypervariable regions, three oligonucleotide PCR primers, known as LD1, LD2 [5,6], and TEC1 [7], have been introduced to amplify a highly conserved region of the *B. burgdorferi* sensu lato 16S rDNA for its molecular fingerprint identification. In combination with the nested PCR and direct automated DNA sequencing technologies, these genospecies-specific PCR primers are useful in generating reliable materials for sequence alignment analysis using the online GenBank database as the standard for validation of the *B. burgdorferi* sensu lato 16S rDNA [8]. The potential value of their clinical application in confirmation of early Lyme disease spirochetemia has been demonstrated by the results presented in this report.

One potential pitfall in targeting a highly conserved bacterial16S rDNA of the genospecies of *B. burgdorferi* sensu lato for molecular diagnosis of Lyme borrelia spirochetemia is that some environmental bacterial 16S rDNA fragments, which may be present in normal human blood samples [18,19], can be amplified by the chosen PCR primers, especially when the nested PCR technology is employed to increase the detection sensitivity (Figures 2, 3, 4). This kind of potential false positive result generated by a non-specific PCR can be eliminated by routine direct DNA sequencing of all putative PCR-positive materials with their signature sequences validated through online GenBank sequence alignment algorithms (Figure 1).

In one residential suburb where Lyme disease is endemic, we found that 5.4% of the ER/WALKIN patients presenting with Lyme disease-like clinical manifestations were shown to have *B. burgdorferi* spirochetemia while none (0%) of the patients referred to the laboratory from their private doctors' offices with the same differential diagnosis had evidence of spirochetemia when tested by the same procedure. In comparison, only 1.5% of the ER/WALKIN patients in the same group were positive for the 2-tier antibody serology test for Lyme disease while 8.4% of the patients referred from the private doctors' offices were positive for the 2-tier serology test. These findings seem to indicate that the best time for detecting spirochetemia in early Lyme disease is when the onset of the clinical manifestations is noticed by the patient. Such immediate medical attention is probably only available at the ER or WALKIN in most endemic regions. Waiting for a scheduled appointment to the regular private doctor's office may miss the window of opportunity in DNA detection at the time when the Lyme disease bacteria are circulating in the blood, but only briefly.

In our series, 6 of the 7 (85.7%) PCR-detected, DNA sequencing-confirmed Lyme spirochetemic patients did not develop the 2-tier Lyme disease antibodies at the time of initial laboratory testing. Since these patients were all suspected of suffering from Lyme borreliosis based on clinical manifestations alone, they were prescribed a short course of preventive doxycycline while waiting for the laboratory test results. The antibiotics would be discontinued when the 2-tier serology screen test and the PCR test results were both found to be negative. All ER/WALKIN patients were referred back to their regular primary care physicians for follow up, and most private healthcare practitioners did not order additional serology tests for these patients. Therefore, it is not known if these 6 sero-negative, proven spirochetemic patients would turn sero-positive for the 2-tier serology test during their long-term convalescence. If no further follow-up serology tests were ordered, or if the subsequent 2-tier antibody tests turned out to be negative as a result of the initial partial treatment [20,21], these 6 Lyme disease patients would have been classified as having "no evidence of Lyme disease", except for the DNA evidence of Lyme spirochetemia. These clinical observations emphasize the importance of public education in the diagnosis of Lyme borrelial spirochetemia. Early Lyme disease is essentially a patient-initiated laboratory diagnosis under the guidance of an alert physician. The patients generally control the window of

opportunity for the detection of spirochetemia which is transient and brief. The time points of spirochetemia may vary from patient to patient.

Conclusion

We found DNA evidence of *B. burgdorferi* spirochetemia in 7 of 130 (5.4%) ER/WALKIN patients with clinical manifestations of early Lyme disease. During the same period, we found no DNA evidence of spirochetemia in 333 patients who were referred from private physicians' offices for Lyme disease tests. In comparison, 28 of the 333 (8.7%) patients from the private physicians' offices were positive for the 2-tier Lyme disease antibody test whereas only 2 of the 130 (1.5%) ER/WALKIN patients were positive for the 2-tier serology test. Only 1 of the ER/WALKIN patients was positive both for the *B. burgdorferi* DNA and for the 2-tier antibody test at the same time. Based on these findings, we conclude that molecular testing for detection of *B. burgdorferi* spirochetemia should be a supplement to the standard 2-tier serology assay for all ER/WALKIN patients with clinical manifestations of early Lyme disease. Relying on a serology test alone may miss the diagnosis of 85.7% of the early Lyme disease, which can be confirmed by a blood NAAT for spirochetemia.

Abbreviations

TEMP: temperature; CBC: complete blood count; WBC: white blood count; ELEV NEUT: elevated neutrophils; Hx: history; ELISA: Enzyme-linked immunosorbent assay; WB: Western Blot; +: positive; -: negative

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Authors' contributions

SHL conceived of the study, participated in its design and coordination and helped draft the manuscript. VSV, JSV and WJ participated in study conception, data acquisition, and laboratory data analyses. JW and JW participated in study conception, design, and clinical evaluation of patients. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Received: 2 June 2010 Accepted: 1 November 2010
Published: 1 November 2010

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doi:10.1186/1756-0500-3-273
Cite this article as: Lee *et al.*: **Early Lyme disease with spirochetemia - diagnosed by DNA sequencing.** *BMC Research Notes* 2010 **3**:273.